September 23, 2021 - Alaska Board of Pharmacy Meeting - Day 1

Alaska Division of Corporations, Business and Professional Licensing
https://zoom.us/j/99331376055?pwd=UEZSc2FISUNWb3NISkxSRnpxMmhMZz09
Sep 23, 2021 9:00 AM - Sep 23, 2021 4:00 PM AKDT

Table of Contents

STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

September 23-24,

2021 Meeting - Day 1

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Leif Holm, PharmD (Vice Chair)	03/01/2015	03/01/2019	03/01/2023
Lana Bell, RPh (Secretary)	05/31/2016	03/01/2018	03/01/2022
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Justin Ruffridge, PharmD (Chair)	03/01/2020		03/01/2024
Tammy Lindemuth (Public Member)	01/24/2018	03/01/2018	03/01/2025
Sharon Long (Public Member)	03/01/2018		03/01/2022
Ashley Schaber	07/01/2021		03/01/2024

Updated 07/12/2021

AGENDA

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

SEPTEMBER 23, 2021 – DAY 1

Meeting ID: 993 3137 6055
Passcode: 7h0Af6

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Justin Ruffridge
PharmD (Chair)

Leif Holm, *PharmD*
(Vice Chair)

Ashley Schaber,
PharmD

James Henderson, *RPh*

Lana Bell, *RPh*
(Secretary)

Tammy Lindemuth,
Public Member

Sharon Long, *Public Member*

Staff:

Laura Carrillo,
Executive Administrator

Lisa Sherrell, PDMP
Program Coordinator

Heather Noe,
Occupational Licensing Examiner

Upcoming Meetings:

November 18-19, 2022 (Anchorage)

February 17-18, 2022 (Juneau)

Meeting Details

Meeting Name: September 23, 2021 - Alaska Board of Pharmacy Meeting - Day 1

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 09/23/2021

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 09/23/2021

Meeting Location: Robert Atwood Building Suite TBD, 550 West 7th Ave, Anchorage, Alaska; Videoconference via Zoom

Meeting Registration Link:

https://zoom.us/j/99331376055?pwd=UEZSc2FISUNWb3NISkxSRnpxMmhMZz09

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Ruffridge)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Ruffridge)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Ruffridge)
IV. Agenda Item #4 – 9:10 a.m. Review/Approve Meeting Minutes (Chair Ruffridge)
    a. May 20-21, 2021
    b. August 12, 2021
V. Agenda Item #5 – 9:15 a.m. PDMP Update (Lisa Sherrell)

a. PDMP – Pharmacy Report
b. Database Updates
c. Education and Outreach

VI. Agenda Item #6 – 10:00 a.m. Investigative Update (Michael Bowles)
a. Case Review Training
b. Investigative Report
c. Imposition of Civil Fines
d. Voluntary Surrender
e. Review Updated Inspection Checklist
f. Consent agreement (Marilyn Zimmerman)

VII. Agenda Item #7 – 11:15 a.m. Public Comment #1

VIII. Agenda Item #8 – 11:30 a.m. Board Business (Chair Ruffridge)
a. Application Review
b. Review Lost/Stolen Rx
c. Review/Approve 2022 Strategic Plan
d. Correspondence
e. Review Final Annual Report
f. Intern Jurisprudence Questionnaire
g. COVID-19 matters
i. PREP Act amendment – therapeutics
ii. Ivermectin
h. PDMP Disciplinary Matrix

IX. Agenda Item #9 – 1:00 p.m. Lunch

X. Agenda Item #10 – 1:30 p.m. Subcommittee Updates (Chair Ruffridge)
a. Healthcare Board Chairs
b. Controlled Substances Advisory Subcommittee (CSAC)
c. Compounding Subcommittee
d. PDMP Board Chairs

XI. Agenda Item #11 – 2:00 p.m. Division/Budget Update (Melissa Dumas)

XII. Agenda Item #12 – 2:30 p.m. Industry/Profession Updates
a. AKPhA (Molly Gray/Gretchen Glasby)

b. DHSS (Erin Narus/Charles Semling)

XIII. Agenda Item #13 – 3:00 p.m. Administrative Business (Laura Carrillo)

a. License Statistics

b. Form Updates

c. Task List Review

d. Upcoming Travel/Conference/Workshops

XIV. Agenda Item #14 – 3:45 p.m. Public Comment #2

XV. Agenda Item #15 – 4:00 p.m. Recess until September 24 at 9:00 a.m.

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

ETHICS

CONFIDENTIAL

ETHICS SUPERVISOR DETERMINATION FORM

(Board or Commission Member)

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does not or would not violate AS 39.52.110 - .190.

_____

Signature of Designated Ethics Supervisor (Chair)

_____

Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

Note: Disclosure Form must be attached. Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.


Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.


Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.

 The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.

 Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

 Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

 Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

 Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

 John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

 The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

 Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

 The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

 Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

6/19

MINUTES

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING

May 20 - 21, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on May 20-21, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:04 a.m.**

The day 1, **May 20, 2021** videoconference was called to order by Chair, Rich Holt at 9:04 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member (joined at 2:15 p.m.)
James Henderson, RPh #PHAP1683 (joined at 9:25 a.m.)
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner
Greg Francois, Chief Investigator
Sonia Lipker, Lead Investigator
Michael Bowles, Investigator III
Sharon Walsh, Deputy Director

Members from the public present/registered:

Jennifer Schneider, State License Servicing
Sam Curtis, DEA
Thomas Olsen, DEA
Dan Nelson
Lauren Paul, CVS Health
Charles Semling, DHSS
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Medical Center
Lorri Walmsley, Walgreens
Caren Robinson, AkPhA
Jennifer Adams, ISU
Brenda Walker, VA
Molly Gray, Alaska Pharmacists Association
Loren Breen, APG
Cheryl Williams, UBC Pharmacy
Wilson Echin, SPP
Gail Elliott, Kaiser Permanente
Kendra Croker, Cardinal Health

Agenda Item 2 **Review/Approve Agenda** **Time: 9:05 a.m.**

Chair Holt verbally reviewed the agenda for the board and public. Ms. Carrillo clarified that Marilyn Zimmerman, the division's paralegal, would be presenting a matter to the board during Agenda Item #6 after Investigator Bowles' update. Agent Olson would also be joining the board for the Drug Enforcement Administration (DEA) update under Agenda Item #7. Ms. Carrillo also added that the official letter from Dr. Schaber on behalf of the AKPhA regarding white bagging had also been received and added to the Onboard packet for Agenda Item #10, but was not reflected in the public version already published. A slide deck from Melissa DeNoon with the South Dakota PDMP was also added to correspondence for discussion around drug takeback programs.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the May 20, 2021 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			

Tammy Lindemuth	x
James Henderson	x
Sharon Long	x

The motion passed with no further discussion.

Agenda Item 3 **Ethics** **Time: 9:09 a.m.**

There were no ethics to report; however, Chair Holt reminded the board and the public that he currently participates in the biweekly healthcare board chairs meeting as well as the biweekly PDMP board chairs meeting.

Agenda Item 4 **Review/Approve Meeting Minutes** **Time: 9:10 a.m.**

The board reviewed the February 18 and 19, 2021 draft meeting minutes.

Sonia Lipker joined the room at 9:10 a.m.
Greg Francois joined the room at 9:11 a.m.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin, and approved unanimously, it was:

RESOLVED to approve the February 18 - 19 meeting minutes as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with no further discussion.

TASK 1
Ms. Carrillo will send the minutes to Chair Holt for signature and request they be published to the board's meeting page.

Agenda Item 6 **PDMP Update** **Time: 9:14 a.m.**

James Henderson entered the room at 9:25 a.m.

PDMP – Pharmacy Report

Ms. Sherrell provided the board's report. Updates included the new contract with Appriss Health starting on April 1st and the re-launch of the license integration project on June 15th. Ms. Sherrell stated updates to the user manual would be posted soon, which will include instructions on new features implemented as a result of the new contract. Ms. Sherrell reminded the board that the license integration project will assess for discrepancies between the licensing system and the PDMP platform, AWARxE, and will deactivate accounts where there are discrepancies with license #s, license status, and name. New license types had been created during the pandemic, so the file transfer list needs to be updated accordingly. According to the list now, there are about 156 pharmacists that would be deactivated.

As of now, there are 1,082 licensed pharmacist, 736 are registered, and only 716 are directly dispensing. Ms. Sherrell explained the breakdown by role, e.g.: pharmacist, pharmacist-in-charge, IHS dispenser, and VA dispenser. Ms. Sherrell then provided an update on delinquent reporters. The April analysis revealed 17 pharmacies as being delinquent for the first time; letters were sent to all and 10 had returned responses.

Ms. Sherrell reviewed recommendations to prescribing boards, such as using delegates to maximize PDMP use and providing guidance to licensees on judicious prescribing practices and dangerous combinations. The annual Awareness and Feedback questionnaire will be launched this summer, which will help us understand apprehension of usage and provide insight into topics to include in education and outreach. Ms. Sherrell shared that she participated in training with a dentist who provided valuable feedback on their interactions with the PDMP; this provided an opportunity to educate the provider on how to submit a UCF report and how to submit zero reports. Ms. Sherrell stated that in-person education and outreach will start in Juneau with pharmacies and expand to other providers throughout Alaska. Chair Holt expressed that in-person is preferable and more effective, but that logistically, the state may not approve travel. Ms. Sherrell stated there are rollover funds from the previous year to use for education and outreach travel purposes.

Forthcoming updates to the system include a delinquent reporting communications module to notify providers when they had missed a reporting day. Dr. Holm asked about the timeline of the launch, expressing it will be helpful in reducing the number of missed days. Ms. Sherrell stated there are some issues with reporting submission settings that may create false alarm flags of delinquency. For example, a pharmacy may be reporting consistently at 10:00 p.m. and have a system update that causes the report to transmit at 10:15 p.m., which would trigger a delinquent notice. This was an issue with another rollout state that has since been corrected with another state, but there was another issue with delivery language in messaging.

It was also explained that clean-up with prescribing boards also needed to be done because prescribers indicated on their renewals that they were directly dispensing (and therefore required to report), when they weren't actually dispensing. The board of nursing sent a notice to its licensees to clarify dispensing status, and nearly half of them indicated it was an inadvertent mistake. Time is needed to clean up our dispenser/reporter list so those who are not truly dispensing will not receive delinquent notices.

Ms. Gray expressed the report was informative and suggested similar reports be shared with other boards and associations to facilitate connectedness of information. Ms. Sherrell stated there are similar board reports issued to prescribing boards.

About the provider outlier module, Chair Holt inquired whether reports are sent to the provider or to the board, to which Ms. Sherrell clarified it is visible administratively for analysis only. The function will also include the ability to see distances traveled for medications, which may indicate doctor shopping.

Resources

Ms. Carrillo provided a refresher of resources found on the state website, pdmp.alaska.gov, including where to access the data dispensing submission form and a zero-reporting video. Ms. Carrillo reminded the board that zero reporting can only be done via ClearingHouse and stated the user manuals would be updated and posted soon to reflect add-ons as a result of the new contract.

Agenda Item 6 Investigative Update Time: 9:42 a.m.

Investigator Bowles presented the board's report which included activity from February 5th through May 6th. There are 33 open cases and 4 have closed.

Investigator Bowles addressed the recusal document sent to board members and stated that in cases where the matter may advance to a hearing, the board needs to make sure there is no possibility of bias or sway by a reviewing board member for a proposed disciplinary action. Dr. Holm inquired whether board members are allowed to be present for discussion, to which Investigator Bowles affirmed. Chair Holt inquired whether it is an absolute requirement that reviewing board members must recuse themselves from voting because the document from Director Chambers states it is still possible to vote. Chair Holt's understanding is that the reviewing board member can put on record to request to recuse themselves, but that as Chair, he could decline the request. Investigator Bowles highly recommended recusals not be denied. Dr. Ruffridge agreed, stating reviewing board members should be able to vote on a matter if they are already providing a recommendation to the board.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, the board moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with no further discussion.

Off record for executive session at 9: 57 a.m.
On record from executive session at 10:32 a.m.

Upon return from the executive session, Chair Holt clarified no motions were made under executive session.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of $1,000.00 for case #2020-000886, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-000886.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson			x	
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the voluntary pharmacy technician license surrender for case #2021-000085, seconded by Justin Ruffridge and approved unanimously, it was:

RESOLVED to accept the voluntary pharmacy technician license surrender for case #2021-000085.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of $250.00 for case #2020-000360, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-000360.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt			x	
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of $500.00 for case #2020-001064, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			

Justin Ruffridge	x		
Lana Bell	x		
Tammy Lindemuth			x
James Henderson	x		
Sharon Long			x

The motion passed with no further discussion.

On a motion duly made by Lana Bell to approve the imposition of civil fine in the amount of $250.00 for case #2020-000359, seconded by Justin Ruffridge and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

On a motion duly made by Rich Holt to approve the imposition of civil fine in the amount of $250.00 for case #2020-000602, seconded by Lana Bell and approved by the board with one recusal, it was:

RESOLVED to approve the imposition of civil fine for case #2020-001064.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 2
Ms. Carrillo will send the signed imposition of civil fine and voluntary license surrender documents to Chair Holt for his signature then forward the signed documents to Investigator Bowles.

Agenda Item 7 **DEA Update** **Time: 10:45 a.m.**

Ms. Carrillo welcomed the DEA officials, Thomas Olsen, tactical diversion group supervisor and Samuel Curtis, Investigative Analyst. Agent Olsen stated agent Pitt was unable to make the meeting.

Agent Olson shared that the Tactical Diversion Squad, which has been in place since 2016, is identifying problematic prescribing practices in a collaborative effort with the PDMP and division investigators to combat the opioid epidemic. Over the years, the team has identified offenders prescribing high amounts of opioids resulting in adverse outcomes within communities.

Samuel Curtis highlighted that in analyzing mechanisms by which practitioners write prescriptions, they noticed a trend two years ago where doctors and nurses were writing large amounts of prescriptions for 28 to 30-days at one time, sometimes for a 30 day-supply in 3 separate prescriptions written in 90-day intervals, 4 times per year. More recently; however, Mr. Curtis stated the trend has shifted: prescribers are moving away from high daily limits to smaller prescriptions that pharmacies are comfortable filling. In many cases, practitioners are taking what used to be 30-day prescriptions for oxycodone to now prescribing 40 days-supply within a 7-day period. Now, prescriptions are often being filled 2 days early, for example, 7-day prescriptions are being filled after 5 days.

Mr. Curtis also shared that in reviewing the patterns from PDMP data, they are seeing prescriptions written for varying quantities of days, e.g.: every 28 days, then 23, then 26, then 29, then 30; quantities are continuously. The DEA notes that looking at the quantity of pills is not as valuable anymore as providers seem to be doing the math on prescription days to add more prescriptions. The DEA is also seeing more variation in personal details given, for example, variations of different names and different zip codes to receive oxycodone and methadone. Mr. Curtis expounded on this, offering the example that a prescriber will write a prescription for methadone to Sam Curtis at Walmart using a street address and then write another prescription for oxycodone for Samuel Curtis using the PO box address, which creates a channel for same-day prescribing and patient pick-up before reporting systems are able to update these transactions for visibility into the PDMP until the following day. These smaller prescriptions are ones that pharmacists are comfortable filling without realizing there are more opioid pills being dispensed over the course of a month.

Dr. Holm commented he hadn't filled a methadone prescription in a long time and inquired when this co-prescribing trend started. Mr. Curtis stated this has been an existing trend for some time, that it used to be geographically concentrated in one area of Alaska but it is now more spread out. Chair Holt inquired whether the DEA has presented similar updates to the practitioner boards, to which Mr. Curtis stated they have been. Mr. Curtis stated the trend of breaking up prescriptions into smaller day amounts to give patients higher quantities of opioids for a month is a more recent trend seen in the last two months. Agent Olson stated that as they have had success intervening with the most egregious prescribers, other prescribers engaging in problematic behaviors have become more sophisticated; it seems there has been communication between the egregious prescribers with other prescribers on how to continue these practices. Agent Olson stated some prescriptions are being consumed and some are being sold on the street.

Dr. Ruffridge stated he has observed a more recent trend of the 7-day fill becoming a requirement from insurance payers or they will not pay for a larger quantity without a prior authorization. Dr. Ruffridge is concerned providers are writing 7-day fills to avoid prior authorization. Prior authorization allows for review of medications commonly abused and the 7-day supply may avoid this. From the payer perspective, Dr. Ruffridge stated that while the intent may be to help, payers may not realize the burden being placed on the enforcement end and on the pharmacists attempting to notice whether this is contributing to a concerning trend. Mr. Curtis stated this trend isn't specific to one insurance program; it is seen across private payers, military, veteran, and CMS programs. Regardless of practitioner or payer type, Mr. Curtis stated across programs, the DEA is estimating that 30-day prescriptions every 28 days amounts to 13 months of prescriptions. The DEA further estimates that up to 22-months of supply days are put into the hands of patients each year with 7 days prescriptions being filled every 5 days.

Chair Holt also suggested to the DEA that they share updates with the AKPhA. Agent Olson shared that they held a program, Practitioner Diversion Awareness Conference (PDAC) to educate pharmacists on DEA trends in the past. The DEA plans to continue to provide this opportunity to providers. Ms. Gray shared that the AKPhA's next annual conference will be held on February 11-13, 2022, which would be a great opportunity to host a PDAC as the association has hosted this program before.

Ms. Carrillo inquired whether these trends are reflective of what the DEA is seeing nationally or if it is specific to Alaska. Mr. Curtis stated the trends are more specific to Alaska, both the co-prescribing of oxycodone and methadone and the shortening of supply days. Data is showing the DEA that these practices are originating from specific geographic locations and are radiating out from there to other providers. Mr. Curtis added these are providers that have been practicing in the state for 20 or more years, so it is believed these practices are purposeful.

Ms. Carrillo also inquired whether the practices are intentionally done with a nefarious motive, or if the issue is more on the patient drug seeking end. Agent Olson stated that based on the level of awareness of the opioid epidemic, it is hard to imagine providers altering their prescribing practices, including creating separate profiles, out of ignorance, that it is intentional. Mr. Curtis

added that there seems to be conversations between patients and providers leading to mutual decisions to receiving more prescriptions.

Dr. Holm stated he had to step out at 11:30 a.m.

Agenda Item 8 **Public Comment #1** **Time: 11:15 a.m.**

There was nobody on the record for public comment.

Agenda Item 10 **Board Business** **Time: 11:21 a.m.**

With no public comment, the board moved to discussing board business.

Disciplinary matrix

Ms. Carrillo pointed to the disciplinary matrix precedence document put together by the Board of Barbers and Hairdressers as a reference example for the board. Mr. Henderson had requested the board discuss development of a matrix to help guide appropriate decision making for disciplinary actions. As part of this request, Investigator Bowles provided to Ms. Carrillo a copy of more recent disciplinary actions the board has taken. The board reviewed the precedence list.

Chair Holt agreed a disciplinary matrix would be useful, though recommended the board take a little more time to review the decisions that were made. As there were different disciplinary actions taken for the same violations, Chair Holt expressed a need to do a deeper dive into the precedence list to understand the nuances of the cases as there appeared to be varying levels of egregiousness.

Chair Holt recommended that the board members review the precedence list and be prepared to discuss what actions the board may want to add to the disciplinary matrix. Ms. Carrillo stated she would compile a chart and tally the types of actions/reprimands most commonly issued. Chair Hold noted the board had already established a matrix for PDMP-related violations and at some point had established a standard violation for issues related to continuing education. Mr. Henderson recalled this discussion, stating it was a dollar amount per hour of missed continuing education activity.

TASK 3

Ms. Carrillo will create a draft matrix charting the most common types of reprimands on the different types of violations for further discussion at the September meeting.

TASK 4

Ms. Carrillo will look for the decision on fine amounts per hour of missed continuing education and will add it to the September meeting agenda.

Agenda Item 9 **Lunch** **Time: 11:31 a.m.**

Off record for lunch at 11:31 a.m.
On record at 12:19 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair* (joined at 2:07 p.m.)
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member (joined at 2:15 p.m.)
James Henderson, RPh #PHAP1683 (joined at 9:25 a.m.)
Justin Ruffridge, #PHAP1787

Upon return from lunch, Chair Holt shared the update that Ms. Noe was able to find the August 2017 meeting minutes reflecting the discussion of the fine amounts per missed hour of continuing education.

Agenda Item 10 Board Business Time: 12:20 p.m.

Disciplinary matrix
Upon return from lunch, Chair Holt shared the update that Ms. Noe was able to find the August 2017 meeting minutes reflecting the discussion of the fine amounts per missed hour of continuing education. Mr. Henderson inquired about the medical board and nursing board's matrices. Chair Holt stated he was aware the medical board did have a PDMP and general practice matrix.

TASK 5
Ms. Carrillo will retrieve a copy of the Medical Board's matrix and will provide it to the board at their next meeting in September.

Chair Holt shared that the New York licensing boards provide a website for the public to search for disciplinary actions and asked the board of they were aware of any other states that publish these. Ms. Carrillo screen shared how to access the disciplinary actions page, which isn't specific to the Board of Pharmacy but includes any disciplinary actions searchable by quarter. Ms. Carrillo noted the New York search is interactive whereas the CBPL action page is not.

Inspections
Included in the OnBoard packet were items requested from the November, 2020 meeting. Chair Holt recalled for the board that the investigative unit had stated few inspections per year is reasonable cost-wise. The board reviewed the sample letter to pharmacies from the investigative unit notifying them of the status of their inspection. A copy of the inspection template used to assess compliance with established standards and protocols was also included in the packet for review. Chair Holt advised that the board should discuss what aspects the board wants the investigator to focus on.

Mr. Henderson inquired who the investigator would be assigned to perform inspections. Chair Holt asked for a volunteer from the board to partner with Investigator Bowles to engage in training on inspection needs. Ms. Bell offered to train Mr. Bowles.

Chair Holt stated he had provided markups on the inspection template.

TASK 6
Ms. Bell will touch base with Investigator Bowles to review the inspection process.

TASK 7
Ms. Carrillo will locate the inspection template markups from Chair Holt and will incorporate it into the September meeting materials.

TASK 8
All board members will be prepared to provide input on inspection report by the September meeting.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, the board moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with no further discussion. Board staff were authorized to remain in the room.

Off record for executive session at 12:37 p.m.
On record from executive session at 1:44 p.m.

Upon return to the record, Chair Holt clarified that no motions were made during executive session.

Application Review

Ms. Carrillo noted to the board that an applicant requested discussion of their application in executive session. Dr. Ruffridge stated he would recuse from voting due to the applicant being a current employee.

On a motion duly made by Lana Bell in accordance with AS 44.62.310(c)(2), seconded by James Henderson and with unanimous approval, the board moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with no further discussion. Board staff were authorized to remain in the room.

Off record for executive session at 1:47 p.m.
On record from executive session at 2:07 p.m.

Leif Holm joined the board at 2:08 p.m.

Upon return to the record, Chair Holt Clarified that no motions were made in executive session. Dr. Holm stated he would recuse due to not having been present for the application review.

On a motion duly made by Justin Ruffridge to approve the wholesale drug distributor application for Blessings International, #169542, seconded by Lana Bell and approved by the board with one recusal, it was:

> **RESOLVED to approve the license application for Blessings International, #169542.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			

Tammy Lindemuth			x
James Henderson	x		
Sharon Long			x

The motion passed with no further discussion.

TASK 9
Ms. Carrillo will provide the motion minutes to Ms. Noe for issuance of the wholesale drug distributor license for Blessings International, in-process #169542.

For the next application review of pharmacy technician in-process license #164543, Dr. Ruffridge declared a conflict as the applicant is a current employee. Dr. Holm also requested recusal due to not being present for application review. Chair Holt approved these recusals.

On a motion duly made by Richard Holt to approve the pharmacy technician license for, #164543, seconded by James Henderson and approved by the board with one recusal, it was:

RESOLVED to approve the license application for #164543.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm			x	
Richard Holt	x			
Justin Ruffridge			x	
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 10
Ms. Carrillo will provide the motion minutes to Ms. Carlile for issuance of the pharmacy technician license for in-process #164543.

Tammy Lindemuth joined the room at 2:15 p.m.

On a motion duly made by Justin Ruffridge to table the in-process pharmacist application for #147445 pending receipt of a completed application, seconded by Richard Holt and approved unanimously, it was:

RESOLVED to table the license application for #147445.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 11
Ms. Carrillo will follow-up with the applicant for in-process #147445 requesting documents required to complete the application. The application will be placed on the September agenda.

On a motion duly made by Justin Ruffridge to table the reinstatement application for pharmacist, #PHAP1602 pending receipt of a completed application, seconded by James Henderson and approved unanimously, it was:

RESOLVED to table the pharmacist reinstatement application for #PHAP1602.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 12
Ms. Carrillo will follow-up with #PHAP1602 to communicate applicable timelines to proceed with the application. The application will be placed on the September agenda.

Agenda Item 12 **<u>Industry/Profession Updates</u>** **Time: 2:24 p.m.**

AKPhA

Dr. Schaber and Ms. Gray, executive director of the AKPhA were present for an update on upcoming events and status of legislation. Lobbyist, Caren Robinson, was also available to provide updates:

Ms. Gray informed the board there was an inaugural leadership development event scheduled for September 24th at the BP Energy Center and an AKPhA academy of health system pharmacy seminar on September 25th. Ms. Gray added the association is currently accepting proposals for presentations. Ms. Gray then addressed HB 145, which proposed to expand pharmacy practice authority will be rolled over to next session, though it was starting to be looked at as vehicle for other legislation, primarily regarding COVID-19, so was stalled in house rules.

Ms. Robinson expressed optimism for the expansion bill but reiterated that COVID-19 provisions related to mandatory testing and vaccine passports were discussed and potentially weighed down the bill.

Dr. Schaber introduced the issue of white bagging, which she indicated was brought to her attention through ANMC as they were receiving requests from insurance companies to use this process to purchase infusion medications. AKPhA has looked into this and realizes it is a more widespread problem. White bagging is a process where an insurance company doesn't pay a provider or insurance provider but uses a specialty pharmacy. Dr. Schaber highlighted the problems this poses, including the inability of the patient's pharmacy to ensure adequate storage and chain of custody to meet the FDA's Drug Supply Chain Security Act (DSCSA) and negative financial impacts to facilities. Another problematic process is with brown bagging where a patient brings the medication to the infusion center for administration. A third issue, clear bagging is when the health system's own specialty pharmacy delivers the medications directly to the clinic. Chair Holt advised the board that if it wishes to seek changes statutorily, the board should be prepared to make the recommendation. Dr. Schaber pointed out there are examples of recent state legislation, which Ms. Carrillo had included in the board's packet.

DHSS - Medicaid

Ms. Carrillo noted to the board that Dr. Erin Narus wasn't able to make the meeting but provided an update by email:

- This upcoming Monday, May 24 at 1pm, the Division of Health Care Services will be hosting a public scoping meeting related to regulations for the Medicaid Pharmacy Services program.
- Dr. Charles Semling was also on the line to reiterate the importance of attending this meeting.

Agenda Item 13 Budget Report/Division Update Time: 2:34 p.m.

Deputy Director, Sharon Walsh, joined the room at 2:30 p.m.

Deputy Director, Sharon Walsh, joined the board to present their Quarter 3 budget report. As of March 31st, the board's total revenue was at $996,647; non-investigative expenditures were at $231,870, investigative expenditures were at $304,019; indirect expenditures (internal costs, departmental costs, statewide costs such as IT) was $192,331; with the board's ending surplus of $719,527. For the PDMP, Deputy Director Walsh shared that there were $166,915 in non-investigative expenditures with an ending cumulative surplus of $226,768. Chair Holt thanked Deputy Director Walsh for the update and affirmed to the board they are on track financially.

Ms. Carrillo reminded the board that the fingerprint fee will be looked at during the board's next fee analysis as this fee wasn't figured into fee changes when the new facility license types were effective in October 2019.

TASK 13
Ms. Carrillo will follow-up on the fingerprint fees for wholesale drug distributors, outsourcing facilities, and third-party logistics providers.

Deputy Director Walsh also provided an update on HB 145 and the PDMP exemption bill, HB91. HB 145 was in the House Rules Committee and HB 91 didn't get referred out of House Labor and Commerce. As session has ended and special session is beginning, it is the expectation these bills will be rolled over into the second session.

Agenda Item 10 Board Business Time: 2:45 p.m.

Hearing nothing further on division updates, Chair Holt prompted the board to return to the board business agenda item.

Review Lost/Stolen Rx
The board reviewed the reports from Safeway Pharmacy #18118 and Safeway Pharmacy #1821.

Strategic Plan
Ms. Carrillo informed the board that she had taken Ms. Bell's draft document on guiding principles, goals, and strategies and formatted it into a final version for 2021. Ms. Carrillo asked the board for feedback and suggested edits, for which there were none. Ms. Carrillo stated there would be a new 2022 strategic plan for the board to review at their September meeting.

TASK 14
Ms. Carrillo will request a new page for the board's Strategic Plan to be created with the 2021 plan uploaded to it.

TASK 15
Ms. Carrillo will work on the draft 2022 plan for review and discussion at the board's September meeting.

Annual Report

Ms. Carrillo provided the board with a draft of its 2021 Annual Report, due June 30th. Ms. Carrillo pointed out new updates to the report, including SWOTs (strengths, opportunities, weaknesses, and threats) created for licensing and PDMP purposes to help illustrate barriers to progress in achieving goals and objectives in these areas.

Ms. Carrillo stated the report was near done, with only the budgetary recommendations (travel) left. Ms. Carrillo recalled in the 2020 report, travel was included for two board members to attend a compounding conference, so stated she would pencil this into the report. Chair Holt also requested to add budget recommendations for inspections as the board had determined, with guidance from Chief Francois, that 15-20 inspections could be performed every two years. Dr. Ruffridge recommended the NABP Annual Conference in Arizona from May 19 – 22, 2022 be included. Ms. Carrillo also indicated she would pencil in a board member to attend the National Drug Abuse and Heroin Summit "Rx Summit" from April 18 – 21, 2022. Ms. Sherrell also plans to attend this summit with Ms. Carrillo using grant-funds as it is a federally-required deliverable.

TASK 16

Ms. Carrillo will add in budgetary recommendations to the 2021 Annual Report for conference travel and training, including the NABP annual report and district meetings, MPJE workshops, compounding conferences, and the Rx Summit.

TASK 17

Ms. Carrillo will finalize the 2021 Annual Report and submit it to the board for review and approval.

Board of Nursing Letter Update

Ms. Carrillo informed the board that the Board of Nursing met in the beginning of May but was not able to review the board's letter addressing 12 AAC 44.440(c)(2). The Board of Nursing plans to review this at their next meeting scheduled for August. Chair Holt commented that if the Board of Nursing wishes to maintain the regulation, that the Board of Pharmacy may want to consider regulation changes to clarify how pharmacists can manage identifier requirements on prescription labels, for example, adding language stating APRN-issued prescriptions are valid as long as the proper credentials are listed.

TASK 18

Ms. Carrillo will follow-up with the Board of Nursing on their plan to address the board's letter at their next meeting in August.

Correspondence

The board reviewed a vaccine safety document from the FDA and correspondence from the NABP on its Model Act, 503B survey, request for information to Vermont. Ms. Carrillo informed the board she provided a response to the Vermont inquiry, sharing the Alaska Board of Pharmacy does not require pharmacy technicians to be registered to work in 503B facilities.

Additional correspondence for review included a slide deck from Melissa DeNoon with the South Dakota PDMP. Ms. Carrillo explained she met with Ms. DeNoon and members of DHSS OSMAP to discuss involvement in a compr/ehensive drug takeback program. Ms. Carrillo shared that the SD PDMP wrote into their BJA grant application funds to cover drug takeback activities. The Alaska PDMP applied for the same grant, but did not request funds specifically to support this activity; however, Ms. Carrillo explained OSMAP has separate funds to assist with this project. Ms. Carrillo's understanding is the board doesn't have specific statutory authority to regulate this, but that pharmacies wanting to become designated takeback sites would amend their existing DEA registration to seek "Collector" status and follow the DEA's regulations and guidelines. Ms. Carrillo asked for interest from the board and whether there were concerns about liability, since the responsibility of these receptacles would fall to the pharmacist-in-charge.

Ms. Carrillo also noted that in this meeting, it was the request of DHSS to gauge interest from pharmacies through its ListServ. Chair Holt suggested first getting feedback from the department of law as to whether the board can establish an approved mechanism for pharmacies to at least notify the board they are engaging in takeback programs. Chair Holt believes it may be reasonable that authority exists for the board to create a notification requirement through AS 08.80.030(d). Dr. Ruffridge commented he has researched this extensively and that because it can be a complex process, a good approach is to partner with local law enforcement agencies because their rules aren't the same as pharmacies. Ms. Carrillo added that the law enforcement collaboration was also suggested by Ms. DeNoon.

TASK 19
Ms. Carrillo will request legal guidance on whether the board can require pharmacies to notify them if they are engaged in drug takeback programs.

Board nominations
Chair Holt then moved to nominations, reminding the board that his last on the board will be on June 30th. Dr. Holm offered his vote of confidence for Dr. Ruffridge to take on the roll of board chair.

On a motion duly made by Lana Bell to nominate Justin Ruffridge as board chair and approved unanimously, it was:

RESOLVED to nominate Justin Ruffridge as the board chair.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			

James Henderson	x	
Sharon Long		x

The motion passed with no further discussion.

Dr. Holm, Ms. Bell, and Ms. Lindemuth would remain as vice chair, secretary, and chair of the CSAC, respectively.

Agenda Item 11 Work Groups/Subcommittee Updates Time: 3:28 p.m.

COVID-19 board chairs

Chair Holt reminded the board the COVID-19 chairs meeting is continuing to occur biweekly, though it has become more of a general meeting for board chairs during legislative session. Ms. Carrillo provided an update of the most recent board chairs meeting, which included topics around legislative updates, including military and military spouse licensure; the time and effort it takes to be a board member, and professions seeking to expand their practice authority.

CSAC

Ms. Lindemuth stated the CSAC's next meeting will be held in the beginning of June. Ms. Carrillo inquired when a copy of the meeting minutes would be posted as the last published meeting minutes are from 2018. Ms. Lindemuth stated she wrote the minutes and inquired how to post them. Ms. Carrillo recalled that the legislation changing the chair of the CSAC being a Department of Law designee to the Board of Pharmacy's chair or chair's designee was the only change; any administrative duties, including writing meeting minutes, is to be retained within DOL.

TASK 20

Ms. Carrillo will follow-up on expectations for CSAC administrative duties.

Compounding

Dr. Holm stated he and Dr. Ruffridge have not been able to meet.

PDMP board chairs

Chairs from the boards with PDMP requirements continue to meet biweekly. During these meetings, board representatives provide updates and solutions are shared on how to educate licensees about the requirements.

Agenda Item 14 Administrative Business Time: 3:40 p.m.

License statistics

Ms. Carrillo provided the following license statistics as of mid-May:

Pharmacists = 1,057
Interns = 475

Techs = 1,257
In-state pharmacies = 132
Drug rooms = 40
Remote pharmacies = 1
OOS pharmacies = 641
In-state wholesalers = 16
OOS wholesalers = 626
Outsourcing = 32
3PL = 175
Courtesy pharmacists = 12
Courtesy interns = 0
Courtesy techs = 6
Emergency pharmacists = 10
Emergency interns = 0
Emergency techs = 0

Ms. Carrillo then displayed the board's Authorized Emergency Courtesy License Activities document, inquiring whether the board wished to enter an end date to the authorized reason for obtaining a courtesy license. At present, the only authorized reason is for the purpose of providing COVID-19 immunizations, which went into effect on November 6, 2020. Ms. Carrillo clarified that these aren't tied to an emergency declaration as it is in the board's emergency preparedness regulations. Dr. Ruffridge recommended rounding it out at the end of the fiscal year. Mr. Henderson inquired how many licenses were used for this purpose, to which Ms. Carrillo stated there were 12 issued to pharmacists and 6 to technicians, but whether they were actually used is unknown.

On a motion duly made by Justin Ruffridge to cease courtesy license application approvals related to COVID-19 immunizations beginning June 30, 2021, seconded by Tammy Lindemuth and approved unanimously, it was:

> **RESOLVED to end issuance of courtesy licenses for the purpose of providing COVID-19 vaccinations on June 30, 2021.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

TASK 21
Ms. Carrillo will update the board's Authorized Emergency Courtesy License Activities document to provide an end date and will request to take down the courtesy license application on June 30.

Task list review
The board reviewed the task list. Dr. Ruffridge stated he is about a quarter of the way through looking at the board's FAQs to determine which need to be removed and which can be made into position statements.

A brief discussion was had between Chair Holt and Dr. Ruffridge on drafting regulation changes. Chair Holt shared it is helpful to draft regulations in a format as close to drafting format as possible. Ms. Carrillo stated it has been past practice to append agreed upon regulatory changes to the minutes. Dr. Ruffridge inquired whether it's possible to append markups to the most current version of the published statutes and regulations booklet.

TASK 22
Ms. Carrillo will inquire with the regulations specialist whether it is possible to include most recent regulatory markups in published statutes and regulations.

Upcoming travel/conference/workshops
The following events are upcoming:

MPJE Review Committee (not state-specific) – June 1 – 11, 2021
Program Review and Training (staff only) – June 15, 2021

Task 23
Ms. Carrillo will plan to attend the staff NABP training on June 15th.

Agenda Item 15 Public Comment #2 **Time: 4:00 p.m.**

Ms. Sherrell inquired about the use of medication disposal bags in the PDMP education and outreach plan, asking for input on whether it would be helpful to send bags to pharmacies for distribution to their patients and if there was a specific brand that was most effective. Chair Holt agreed it would be useful, adding that if there was a bag available for every prescription, he would provide one. Chair Holt suggested either Dettera or DisposeRx. Dr. Ruffridge added that he received a grant for 1,500 Mallinckrodt disposal bags several years ago and it was well received in the community. Pharmacist, Dan Nelson shared that Alaska Native Medical Center (ANMC) previously received a large stock of Deterra disposal bags, which were handed out for some time and especially helpful in rural areas. Dr. Nelson added that when clinics were in need of more, they could reach out to ask.

Lorri Walsmley from Walgreens shared an invite to the meeting for districts 6, 7, and 8 from August 29 to 31st in Phoenix. Ms. Walmsley added she could send out the attendance link and agenda.

Pharmacist, Jordan Hussey inquired about the process for being selected as a board member. Chair Holt described the process of applying, sending resumes, participating in interviews, sending the list to the Governor's Chief of Staff, then going through the legislative confirmation office to confirm.

Agenda Item 16 **Adjourn** **Time: 4:15 p.m.**

The board recessed at 4:15 p.m.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING

May 20 - 21, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on May 20-21, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:03 a.m.**

The day 2, **May 21, 2021** videoconference was called to order by Chair, Rich Holt at 9:03 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
James Henderson, RPh #PHAP1683
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner

Members from the public present/registered:

AAG Megyn Weigand, Department of Law
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Medical Center
Lorri Walmsley, Walgreens
Molly Gray, Alaska Pharmacists Association

Agenda Item 2 **Review/Approve Agenda** **Time: 9:04 a.m.**

Chair Holt reviewed the agenda. Ms. Carrillo added that AAG Megyn Weigand would be present to discuss the negative implication canon at 9:30 a.m. under Agenda Item #5 as a follow-up from the board's February meeting. Ms. Carrillo also recommended to add the discussion of PDMP reporting compliance recommendations and the board's disciplinary matrix under Agenda Item #8. Chair Holt clarified the discussion of white bagging would be statute related discussed under Agenda Item #9.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the May 21, 2021 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

Agenda Item 3 **Ethics** **Time: 9:09 a.m.**

There were no ethics to report.

Agenda Item 4 **Public Comment #3** **Time: 9:15 a.m.**

Ms. Gray inquired whether she should announce there will be a board member position open in light of Chair Holt leaving at the end of June. Chair Holt believes it's appropriate to inform AKPhA members a position would be available soon. Dr. Ruffridge stated he submitted his application when membership was full but was still able to proceed with the process and recommended interested applicants apply now as there will be additional openings in the near future.

Dr. Schaber inquired about automated dispensing kiosks and the required placement of them in relation to a pharmacy, citing discussion around the 10 feet rule. Chair Holt clarified that the board's inquiry into whether regulating automated dispensing kiosks was within their authority resulted in guidance from the Department of Law to include distance requirements for installing

these. The board has not implemented a 10 feet rule as of yet but automated dispensing kiosks regulations are in draft form and will be discussed in the future.

Agenda Item 5 Legal Opinion Updates Time: 9:26 a.m.

AAG Weigand joined the room at 9:32 a.m.

Expedited partner therapy

The board reviewed guidance on issuing expedited partner therapy. Ultimately, pharmacists are still required to obtain the patient's information prior to dispensing medication, which would include partners; without this information, the prescription order cannot legally be filled. DOL suggests the board amend 12 AAC 52.460 to exempt partner information from being obtained for partner therapies. Dr. Ruffridge expressed concern about patient safety and instead suggested a new regulation section on partner therapy so the board can address allergies, contraindications, and other verbiage to address standards for patient safety.

Negative implication canon

This topic is in follow-up to the board's February meeting. Dr. Ruffridge inquired how applicable this canon is in all measures of statute and regulation projects because it doesn't seem most people are aware of this and that there are significant implications. In testimony for HB 145, for example, medical providers felt strongly that language was added to ensure limitations were placed on pharmacist prescribing, though Dr. Ruffridge's opinion is that it's not necessary to specify what is limited. AAG Weigand stated the canon is always applicable; when statements are affirmatively provided in a list, this means other areas not included in the list are automatically excluded. AAG Weigand added that one way we can avoid implications of this canon are to make a non-inclusive list, e.g.: "including", which already means including but not limited to; they are only providing examples.

Medication management of out-of-state pharmacies

The board reviewed the guidance from DOL, which provides that out-of-state pharmacies cannot engage in telepharmacy services because a telepharmacy system can only be used by central and remote pharmacies under direct supervision of a pharmacist located in Alaska. Chair Holt recommended that statutory changes be made to regulate telepharmacies, much in the same way the board would need to seek legislative change to know what Internet pharmacies are providing services to Alaska. Chair Holt reminded the board that Alaska only registers non-resident pharmacies, which limits the board's ability to enforce and discipline. It has been the board's interest to seek legislative change to license rather than register these pharmacies.

Chair Holt also recommended clarifying in statute or regulation what activities constitute telepharmacy services. Mr. Henderson agreed with these changes as it would provide much needed clarity to the board. Ms. Lindemuth also expressed that legislative change would be ideal; with tele-services growing, the board should be statutorily prepared to address concerns and avoid any loopholes that might otherwise be present. Ms. Carrillo suggested these items could possibly be rolled into HB 145 for second session. Ms. Gray commented there is a telehealth bill, SB78, which

could also include telepharmacy services next session. Ms. Gary also informed the board of Governor-introduced SB93 and HB13 for a payer healthcare database under the Division of Insurance, adding these may also be vehicles to introduce telepharmacy legislation.

Chair Holt stated if it is the will of the board to seek changes through a Governor's bill, language would need to be prepared by July. Chair Holt added that it would be timely to also update the definition of "drug" to include compressed gasses and blood banks through legislative change.

Medicolegal investigative access

Ms. Carrillo addressed medical/coroner's access to PDMP information. Guidance was previously provided clarifying medicolegal investigators within the M/CO office can also have acess to the data. At present, access is through direct login credentials. The basis of the follow-up on this guidance is to determine whether a subpoena is required since other investigator, for example, CBPL and DEA investigators, must submit a subpoena.

Chair Holt called for a brief break.

Off record at 10:55 a.m.
On record at 11:08 a.m.

Upon return from record, it was clarified Ms. Lindemuth would be out for the rest of the meeting.

Collaborative practice agreements

The board reviewed the guidance on approval of collaborative practice agreements through the board's executive administrator (EA). As written, 12 AAC 52.240 doesn't allow the EA to approve these; however, if this section was amended to create a checklist of required items and if the EA regulation, 12 AAC 52.993, was amended to add approval of these agreements, the board's preference to administratively approve these would be met, rather than requiring full board approval as per the State Medical Board's corresponding regulations in 12 AAC 40.983(k). Ms. Carrillo added that later on in the agenda, there will be further discussion on a proposed collaborative agreement join approval process with the Medical Board.

Agenda Item 6 Regulations Update Time: 11:02 a.m.

- 12 AAC 52.990 - Display of licenses – The board discussed this and landed on the following amendment: "A licensee shall retain all licenses, certifications, registrations, or permits in the practice site. This documentation shall be made available to the board, law enforcement, or inspector upon request. The division's licensing website printout confirming active credentials is acceptable in lieu of a printed document."
- 12 AAC 52 (new) - Drug and device expiration date on labels - Chair Holt inquired if the board would be interested in mandating expiration dates are on labels, which Dr. Ruffridge agreed would be beneficial for patient safety. Mr. Henderson's thought was that most pharmacies already indicate the expiration date on their label, to which Chair Holt stated

was standard practice for some pharmacies but not might be for all. Chair Holt confirmed it is standard in some pharmacies but can't speak to all others. Dr. Ruffridge stated the FDA's 1979 law sets expiration dates and recommended the board could consider adding a separate expiration dates for unit dosed medication packs, which should have a much shorter expiration date than the one year.

TASK 24

Chair Holt will put language together addressing expiration dates into 12 AAC 52.480 for the board's consideration at their next meeting in September.

- 12 AAC 52 (New) - Facility standards for equipment and supplies - "all pharmacies have in their possession the equipment and supplies necessary to engage in the practice of pharmacy relevant to the pharmacy services offered. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.
- 12 AAC 52 (New) – Inspections – the board reviewed Chair Holt's suggested language for inspections, which included language requiring that for pharmacies in which findings are discovered during the inspection process, the discrepancies will need to be addressed within a certain timeframe. Ms. Bell suggested suggesting giving pharmacies and facilities 90 days to correct the issues or submit a corrective action plan. Mr. Henderson inquired whether this would be enough time and recommended the plan be approved by the board.

  To clarify this applies to pharmacies and facilities located in the state and authorized CBPL investigators to perform inspections, Ms. Carrillo suggested amending this to read, "A wholesale drug distributor, pharmacy, drug room, or remote pharmacy located in this state shall permit an authorized investigator assigned to the board, who shows proper identification, to enter and inspect the facility at reasonable times and in a reasonable manner, and to inspect the pharmacy or facility's record and written operating procedures. Ms. Carrillo inquired about the chain of events, for example, whether the inspection report with findings needs to be reviewed by the board before being notified they must address the discrepancies or if the pharmacy/facility can simply receive the findings, correct them, then notify the board or investigator that they have been corrected. Ms. Bell envisioned the investigator would identify the discrepancies and the pharmacy/facility would submit a correct action plan. Ms. Bell inquired whether there should be a penalty for discrepancies.

  Mr. Henderson also inquired whether the inspector would then need to go out and verify the pharmacy/facility did in fact correct the discrepancies, suggesting we may need to institute a fee if the investigator is expected to perform a subsequent review. Dr. Ruffridge believes 30 days is more appropriate and that the inspector should not go back out a 2nd time for the pharmacy/facility to prove that corrections were made. Instead, Dr. Ruffridge states simply acknowledging that corrections is needed would be sufficient, but that if pharmacies/facilities show up as deficient multiple times, the board could assess a fine.

Chair Holt suggested requiring a notification form so there is a record of acknowledging the discrepancy.

Dr. Ruffridge believes the board is financially solvent to provide inspection services using its surplus without implementing a separate inspection fee, but agreed an analysis would be useful. Chair Holt recalled investigations had indicated 10 – 15 inspections per year was doable, adding previous investigator, Mr. Howes had been doing these. Ms. Carrillo inquired whether inspections were done in the Anchorage and surrounding areas or if travel was involved, which might increase the cost.

TASK 25
Ms. Carrillo will create a draft notification form acknowledging discrepancies of an inspection and will present it to the board at their September meeting.

TASK 26
Ms. Carrillo will look into the cost of the inspections if the board were to do 10-15 inspections and will add this into the board's annual report.

Agenda Item 7 Lunch **Time: 12:01 p.m.**

Chair Holt called for lunch at 12:01p.m.
Back on record at 1:04 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Lana Bell, RPh #PHAP893
James Henderson, RPh #PHAP1683
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner

Agenda Item 8 PDMP Regulations **Time: 1:06 p.m.**

Registration (May 6, 2021)
Ms. Carrillo reviewed the changes to 12 AAC 52.855 regarding registration, which went into effect on May 6th and now requires providers to register with the PDMP within 30 days of meeting the mandatory registration requirement. The amendment also includes a requirement for non-

dispensing pharmacists to submit a dispensation exemption form within 30 days of licensure if the pharmacist does not plan to dispense controlled substances in the state. update to the registration regulations, which went into effect on May 6th for all licensees required to register with the PDMP. Add to disciplinary matrix.

Renewal and notifications

The board previously discussed additional changes to PDMP regulations during its February meeting and had left off on discussing language related to the registration process. The board discussed use of secure email accounts and ultimately landed on "non-shared email address" to align with existing the existing end user language agreement (EULA). The board also previously addressed the need to include language regarding delegates and renewal, as both exist but are not codified.

Ms. Carrillo provided draft language, including a section on notifying the board within 10 days of a change in dispensing or distributing status by pharmacies and pharmacists. Chair Holt inquired whether the intent is to assist in reporting compliance clean-up. Ms. Carrillo recalled that during the previous meeting, Ms. Bell inquired whether pharmacies can report when they are no longer dispensing or distributing controlled substances. Presently, the main opportunity is every two years at renewal, though licensees could notify us in writing at any time. Ms. Carrillo added that when pharmacy reporting analyses started in January and Ms. Sherrell was following up with pharmacies receiving a notice of delinquency, several pharmacies had responded they were dispensing/distributing at the time of their renewal but had since stopped. This notification would assist in timely and more accurate status capture of dispensing/distributing and avoid sending notices to licensees where reporting doesn't apply. Ms. Carrillo added that the 10 days was suggested because there is also a 10-day PIC change timeframe.

Chair Holt further inquired whether receipt of these notices will prompt removal of the licensee from the PDMP. Ms. Carrillo stated pharmacists would be removed if they are no longer dispensing. Ms. Sherrell clarified we would also manually remove pharmacies from Compliance Reporting in AWARxE as license integration won't automatically deactivate these accounts. Ms. Carrillo commented that if a similar integration project between the compliance function in AWARxE and the dispensing/DEA designations in Portal was implemented, it would be helpful and worth pursuing in the feature.

Regarding delegate access, Chair Holt inquired about the process for this and whether a form is required. Ms. Sherrell clarified that delegates aren't required to pay or submit a form; as long as the delegate is regulated under AS 08 and at least one supervising provider has approved their account, admin will approve the delegate to have access. Mr. Henderson inquired whether the board wished to clarify the role of delegates among all provider types, including veterinarians, nurses, doctors, etc. Ms. Carrillo suggested a separate regulations section on delegates might be appropriate; providers have expressed a desire to appoint a delegate for the purpose of that delegate reviewing how a provider's treatment practices aligns with their institutional prescribing practices; however, quality review isn't the intent of delegate access. Ms. Carrillo stated the intent

is for delegates to review and report for patients they are involved in a treating relationship with under the supervision of their practitioner. Dr. Ruffridge commented a new section may not be necessary since delegates are able to have the same abilities as the supervising provider. It was ultimately decided not to create a separate section for delegate access at this time.

Supply day exemptions to reviewing and reporting

Ms. Carrillo addressed AS 17.30.200(k)(A), inquiring whether it is the intent for any supply day to be exempt from being reviewed in these scenarios as these are not tied specifically to any supply day as is (B). Chair Holt stated it would be appropriate to defer to prescribing boards as to what supply days don't have to be reviewed. Ms. Sherrell added that we have in the past referred licensees to their prescribing boards, but the boards did not know either. Ms. Carrillo added that (B) implies any non-refillable prescription intended to last more than 3 days must be reviewed.

Ms. Carrillo addressed AS 17.30.200(t), also inquiring whether a (1)(A)(B) constitutes exempted reporting for any supply day. Ms. Carrillo also asked the board if their understanding of (2)(A)(B) means that providers working in inpatient pharmacies or emergency departments must comply with the reporting requirement if the outpatient supply is for more than 24 hours. Dr. Ruffridge stated there typically aren't instances where inpatient pharmacies dispense more than a 24-hour supply because they are prepackaged. The board agreed emergency providers issuing any prescription more than a 24-hour supply is to be reported.

TASK 27

Ms. Carrillo will clarify with the prescribing board chairs that AS 17.30.200(t) requires prescriptions written for more than a 24-hour supply to be reported.

On a motion duly made by Justin Ruffridge to approve the PDMP regulations as discussed for cursory review by the Department of Law, seconded by Rich Holt, and approved unanimously, it was:

> **RESOLVED to accept the proposed PDMP regulation amendments for cursory review by the Department of Law.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Sharon Long				x

The motion passed with no further discussion.

12 AAC 52.855. Registration with the prescription drug monitoring program controlled substance prescription database. (a) A prescriber shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

(b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration must be completed not later than 30 days after initial licensure if the pharmacist's practice is expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a PDMP dispensation exemption form provided by the board. A pharmacist who submitted a dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP [WEBSITE; AND] by **providing**

A. a non-shared email address;

B. password;

C. user role;

D. healthcare specialty;

E. the drug enforcement administration (DEA) number issued to the prescriber, or if a pharmacist, the employer's DEA; and

(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a [USER ACCOUNT, LOGIN NAME, AND PASSWORD BY THE DEPARTMENT] **registration number**.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the [USER ACCOUNT, LOGIN NAME, AND PASSWORD ISSUED BY THE DEPARTMENT] **credentials created in (c)(1)(A)(B) of this section**.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.____ PDMP Registration Renewal (NEW) (a) A registration will expire on the same date as the pharmacist's or practitioner's corresponding professional license.

(b) To renew a registration, a licensee required to register must submit the fee established in 12 AAC 02.107 on or before the expiration date.

12 AAC 52.___ Change in Dispensing or Distributing of Controlled Substances (NEW) (a) a pharmacist registered with the PDMP under 12 AAC 52.855 must notify the board on a form provided by the

department when the pharmacist no longer dispenses controlled substances in the state within 10 days of the change in dispensing status.

(b) a pharmacist who submitted the dispensation exemption form in 12 AAC 52.855(b) who begins dispensing controlled substances in the state must notify the board on a form provided by the department and register with the PDMP within 10 days of the change in dispensing status.

(c) a pharmacy required to report to the PDMP that no longer dispenses or distributes controlled substances in or to the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

(d) a pharmacy that obtains a DEA registration after its license or registration is initially granted by the board and intends to dispense or distribute controlled substances in the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

12 AAC 52.____ PDMP Registration Renewal (NEW) (a) A registration will expire on the same date as the pharmacist's or practitioner's corresponding professional license.

(b) To renew a registration, a licensee required to register must submit the fee established in 12 AAC 02.107 on or before the expiration date.

12 AAC 52.___ Change in Dispensing or Distributing of Controlled Substances (NEW) (a) a pharmacist registered with the PDMP under 12 AAC 52.855 must notify the board on a form provided by the department when the pharmacist no longer dispenses controlled substances in the state within 10 days of the change in dispensing status.

(b) a pharmacist who submitted the dispensation exemption form in 12 AAC 52.855(b) who begins dispensing controlled substances in the state must comply with the requirements in 12 AAC 52.855(c) within 10 days of the change in dispensing status.

(c) a pharmacy required to report to the PDMP that no longer dispenses or distributes controlled substances in or to the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

(d) a pharmacy that obtains a DEA registration after its license or registration is initially granted by the board and intends to dispense or distribute controlled substances in the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

TASK 28

Ms. Carrillo will forward the approved PDMP regulation amendments to the regulations specialist to request cursory review by the Department of Law and will append the changes to the minutes.

Reporting limitations and recommendations

Ms. Carrillo and Ms. Sherrell drafted a process summary of challenges to monitoring PDMP reporting compliance and recommendations for how to improve this. As a recap, the board previously defined "continuous delinquency" as pharmacies appearing in subsequent quarterly delinquent pharmacy analysis lists as well as pharmacies who have been notified of their delinquencies but have not attempted to respond to the notice or attempted to correct the data.

It was recommended the board revisit their compliance analysis as the primary limitations are that analytics functions only display a 30-day lookback period and the system doesn't display when a pharmacy has since submitted missed data or corrected errored data. Another issue discovered is that the system only allows admin to enter a static date for running delinquency reports; it was previously believed that the date entered would display all the pharmacies flagged as delinquent for every day up until that date; however, the results actually display pharmacies that were delinquent on a specific date. PDMP staff have asked Appriss to add the ability to enter dynamic timeframes as opposed to one single date.

Ms. Sherrell stated that in most cases, pharmacies don't just appear on the list once; pharmacies typically are delinquent for many days. Ms. Sherrell added that the communications reporting module will likely resolve delinquencies, to which Dr. Holm agreed.

Ms. Carrillo stated that in light of the new information on limitations with monitoring and not knowing whether any data has since been corrected, she did not yet forward the 50 or so potential delinquent pharmacies to the Investigations Unit during the April analysis. The 17 pharmacies who appeared as delinquent for the first time were notified and Ms. Sherrell has been in follow-up. Ms. Sherrell reiterated that the problem isn't that we can't forward potential non-compliance matters to Investigations, it's that PDMP staff wouldn't be able to confirm whether any of the pharmacies had since corrected the data without allocating a significant amount of datamining work. Notices that missing data has since been submitted is not a feature of the current system; there is no automation to inform staff of when the data has been corrected. Chair Holt and Dr. Ruffridge expressed frustration and disbelief in these limitations. Ms. Carrillo shared Appriss is aware of the limitations and are finding ways to strategize solutions. Dr. Ruffridge stated there should be a way for pharmacies to easily login and see a green checkmark when a submission has been successfully reported.

Ms. Carrillo commented the board may need to amend its disciplinary matrix if it is agreed that analysis of compliance should change from quarterly to monthly. As included in the recommendations document, Ms. Carrillo shared that simplifying the non-compliance criteria by grouping licensees into dichotomous categories (was a report submitted? yes/no) would help align with system capabilities, though it may be unpopular because this approach doesn't take into account the egregiousness of the missing data; rather, it categorizes pharmacies into a box of whether or not they missed one day of reporting, regardless of how many prescriptions were not reported, what types of drugs were not reported, and what the schedules were.

The board continued to discuss the issues. Ms. Sherrell suggested the reports would need to be run daily and then on a monthly basis, all the pharmacies who ever appeared as delinquent on at least one day would be forwarded to the Investigative Unit. Mr. Henderson inquired if it would matter if the pharmacy fixed the data the next day, to which Ms. Sherrell stated they would still be non-compliant for missing the reporting day. Dr. Ruffridge added that within the disciplinary matrix, the part about responding to the notice—whether through contacting the office or correcting the data—would need to be removed. Chair Holt suggested requesting guidance from DOL on whether we can require pharmacies to respond to notices of delinquency. Ms. Carrillo stated a certified mail letter is an official way to provide notice to licensees.

Ms. Bell inquired about what other boards have done to address reporting non-compliance. Ms. Carrillo explained they are beginning to track licensees required to report but have not yet defined non-compliance parameters. Ms. Carrillo commented that as the board of pharmacy smooths out their process, it can be shared with the prescribing boards. Dr. Ruffridge asked if other prescribing boards have to analyze their data, to which Ms. Sherrell and Ms. Carrillo stated they don't; it is just them, but that the bulk of the work will be upfront and it should get smoother as more providers become compliant and boards establish their own processes. The board discussed when to start the new daily running of reports for monthly referrals. Ms. Carrillo stated that since licensees were made aware of the board's quarterly analysis plan in September, a similar notice should be sent informing licensees of the new process. Ms. Sherrell suggested a do-over would be appropriate if

new criteria for delinquency is being established. Chair Holt recommended that for the first month, licensees are notified they are missing data, and that in subsequent months, licensees will be referred to the investigative unit. The board discussed that the fine would be imposed only in subsequent appearances as a delinquent reporter.

TASK 29
Ms. Carrillo will update the board's PDMP disciplinary matrix to reflect daily tracking of reporting compliance for monthly referrals to the Investigative Unit.

TASK 30
Laura will draft letter of new plan and will send the notice to the board for review/approval with the aim to mail it out on June 1st.

Agenda Item 9 Potential Statute Changes Time: 3:30 p.m.

White bagging
The board returned to discussion of white bagging, which was a topic presented by Dr. Schaber on day 1. Chair Holt clarified it would require a statute change. Ms. Carrillo commented it may be a legislative change with division of insurance under Title 21. Chair Holt encouraged the board to think about the different avenues of pursuing this: seeking support in the next 2 months for a proposal as a Governor's bill; to work with the association to add onto HB145 in the second session; or to act independently as a board to find its own sponsors. Chair Holt stated that if it is the will of the board to try to seek the Governor's support, that a meeting within the next 30-45 days would be ideal.

Ms. Carrillo asked for clarification on brown bagging, to which Dr. Schaber stated is when medication is shipped to the patient, and the patient then goes to the hospital to have prescription administered there. Dr. Schaber added that this is commonly seen in infusion pharmacies. Mr. Henderson inquired whether white bagging and brown bagging is the same. Dr. Schaber clarified that this is when a payer requires the hospital to purchase from a specific specialty pharmacy and then ships that to the hospital for administration to the patient. White bagging is distinguished from brown bagging in that only the latter involves direct shipment to the patient.

Chair Holt recommended the board review other state's legislation. Included in the board's packet were an ASHP slide deck from April 2021including examples of state legislation. Dr. Schaber stated Texas and Virginia had passed legislation, so it would be most useful to look at their language.

Outstanding statute project
Chair Holt reviewed the board's pending legislative changes the board has previously discussed but as potential amendments but not yet officially approved to move forward. Among these topics are requirements related to affidavits of moral character, licensing versus registration of out-of-

state pharmacies, prohibiting the use of the term "apothecary" by unlicensed pharmacies, and automated dispensing machines.

Agenda Item 6 **Regulations Update** **Time: 3:58 p.m.**

Ms. Carrillo reviewed the cooperative practice improvement plan she developed with Natalie Norberg, EA for the State Medical Board. The board of pharmacy had developed its own process for reviewing and approving these applications because the medical board hadn't been approving them; however, the Medical Board recently revisited this topic and wishes to become more involved. The improvement plan outlines how cooperative practice agreements relates to HB 145 and a plan for next administrative steps. As part of next steps, Ms. Carrillo provided a markup of the board's collaborative practice regulations in 12 AAC 52.240, which strikes most of the language because it is not necessary to verbatim have what the Medical Board has in their cooperative practice agreement regulations in 12 AAC 40.983. Ms. Carrillo also created form markups to merge the board of pharmacy's form and the medical board's form.

Ms. Carrillo explained that the idea is the State Medical Board would have primary approval of the cooperative practice agreement application, and once approved, it would be forwarded to the board of pharmacy to be endorsed by the EA. The hope is that this would also be another avenue to avoid full-board approval as previously described in day 1.

Chair Holt cautioned that the language may only relate to medical board licensees, but that most of the agreement applications are coming from Board of Nursing licensees. Ms. Carrillo acknowledged this, stating she recently reignited cooperative/collaborative practice agreements with the prescribing boards since the language states it involves providers with the authority to prescribe rather than specifying the type of healthcare provider.

Ms. Bell inquired whether pharmacists from IHS facilities can participate in collaborative relationships without seeking board approval. Ms. Bell was asked by an IHS-employed pharmacist about this and didn't believe approval was required. Chair Holt recalled previous discussions on what requirements the board could hold licensees to who were employed by the HIS.

TASK 31
Ms. Carrillo will follow up with EA Norberg on the Medical Board's discussion of the joint cooperative practice agreement plan.

TASK 32
Ms. Carrillo will follow-up with the Board of Nursing, Board of Dental Examiners, and Board of Examiners in Optometry on their intent to pursue similar cooperative practice agreement regulations. Ms. Carrillo will provide an update at the September meeting.

TASK 33

Ms. Bell will provide language to Ms. Carrillo on a potential request to DOL regarding IHS pharmacists and collaborative practice agreements.

Agenda Item 13 **Public Comment #4** **Time: 4:00 p.m.**

Lorri Walmsley inquired on what the board's legislative priorities are, and if it includes technician immunizations. Chair Holt stated these were addressed via emergency preparedness regulations.

Agenda Item 11 **Farewell Chair Holt/Upcoming Meetings** **Time: 4:10 p.m**

Farewell Dr. Holt

Day 2 of this meeting marks Chair Holt's last meeting day after several productive years on the board. Ms. Carrillo thanked Dr. Holt for his commitment to the board and expressed gratitude for how knowledgeable, accessible, dedicated, and proactive he has been for the board and pharmacy profession. Ms. Bell, Mr. Henderson, and Dr. Ruffridge expressed their thanks with similar sentiments that he has been an exceptional chair and will be sorely missed.

Chair Holt expressed his gratitude for the opportunity to serve on the board, adding it has been a wonderful experience. Chair Holt expressed he would still participate when he can through providing comment on regulations, maybe eventually returning to Alaska.

Next meeting dates

September 23 – 24th – Anchorage
November 18 – 19th – Anchorage
February 17-18 – Juneau

TASK 34

Ms. Carrillo will submit travel requests for the September and November meetings in Anchorage and February 2022 meeting in Juneau.

Agenda Item 9 **Adjourn** **Time: 4:28 p.m.**

On a motion duly made by Lana Bell, seconded by James Henderson, and approved unanimously to adjourn the meeting, the meeting was adjourned at 4:28 p.m.

_____

Laura Carrillo, Executive Administrator Date

_____

Justin Ruffridge, Chair Date

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE EMERGENCY MEETING

August 12, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on August 12, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 2:18 p.m.**

The day 1, **August 12, 2021** videoconference was called to order by Chair, Dr. Ruffridge at 2:18 p.m.

Board members present, constituting a quorum:

Justin Ruffridge, PharmD #PHAP1787
Ashley Schaber, PharmD, #PHAP1697
Lana Bell, RPh #PHAP893
James Henderson, RPh #PHAP1683 – *joined at 2:18*
Tammy Lindemuth – *joined at 2:30 p.m.*

Division staff present:

Laura Carrillo, Executive Administrator
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner

Members from the public present/registered:

Lorri Walmsley, Walgreens
Gail Elliott
Rachel Cole
Maimuna Bruce

Agenda Item 2 **Review/Approve Agenda** **Time: 2:20 p.m.**

Dr. Ruffridge reviewed the brief agenda and called for a motion.

On a motion duly made by James Henderson to approve the meeting agenda, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to accept the August 12, 2021 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

Agenda Item 3 **Ethics Disclosures** **Time: 2:21 p.m.**

Dr. Schaber is a member of AKPhA and am the Past-President (incl. Board Member; By-Laws & Nominations Committee Chair) (through 2/22); Co-treasurer (through 2/22); and a member of the Legislative & Convention Committees.

Agenda Item 4 **Review/Discuss Renewal Process** **Time: 2:23 p.m.**

Ms. Carrillo provided background on the renewal review process position statement, clarifying it is adapted from the division's administrative process for reviewing and approving renewal applications with affirmative responses to the Professional Fitness section. This section relates to criminal history, license actions, and sometimes questions related to physical and mental health. The board ultimately believed it should be amended to include other egregious crimes where renewing a license would pose a danger to the public.

On a motion duly made by Lana Bell to approve the renewal process position statement as amended, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to approve the renewal process position statement as amended to include 12 AAC 52.925(a)(5)(6)(7), relating to sexual assault, sexual abuse of a minor, and unlawful exploitation of a minor, including possession or distribution of child pornography.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long				x

The motion passed with no further discussion.

TASK 1
Ms. Carrillo will amend the renewal document and post it to the board position statement page.

TASK 2
Ms. Carrillo send to the board the completed draft minutes.

Agenda Item 5 **Adjourn** **Time: 3:08 p.m.**

Dr. Ruffridge thanked the board for their participation and reminded them of the upcoming quarterly meeting scheduled September 23rd and 24th in Anchorage.

_____
Laura Carrillo, Executive Administrator Date

_____
Justin Ruffridge, Chair Date

This report contains summary data from the Prescription Drug Monitoring Program (PDMP). Data is provided as a courtesy for the board and is intended to be used for informational purposes only.

Notices

- We received approval for the Provider Outlier Module which will be available by October.
- Appriss is rolling out some changes to the patient report. Changes will be implemented on August 25th. Appriss is sending communication about the changes.
- License integration will be implemented in September.
- The communications module will be rolling out by the end of the year.
- We are continuing to discuss the Delinquent Reporting Notice with the states who have implemented the system and are anticipating enabling this feature. This enhancement will send notices to providers when at least one day of reporting is missed.

There are differences in the number of pharmacists licensed by the Board of Pharmacy and the number of pharmacists registered in the PDMP. The registration counts in the federal user role categories also include non-Alaska licensed pharmacists and some Alaska-licensed pharmacists have opted to register even though not required to by statute and regulations.

Registration

Portal (Professional license system)

Number of licensed Pharmacists: 1,078 (includes 8 Emergency Permits)
Number of PDMP Pharmacist registrations: 745
Number of Pharmacists dispensing: 752

AWARxE (PDMP)

Number registered with the PDMP: 1,044
- Pharmacists – 812
- PIC – 99
- IHS Dispenser – 116
- VA Dispenser - 17

Delinquent Reporters

The process for addressing delinquent reporters is under revision, pending further discussion from the Board of Pharmacy and ongoing work with Appriss.

Recommendations

- Encourage the use of authorized delegates.

Recommendations to Prescribing Boards

- Encourage increased reviewing, including the use of authorized delegates
- Issue periodic reminders to licensees on mandatory reviewing and reporting
- Provide guidance to licensees on prescribing practices related to the use of dangerous combinations
- Set daily MME in regulation
- Develop a plan for communication with licensees about mandatory reporting
- Develop a disciplinary matrix to guide appropriate actions taken against licensees who do not comply with mandatory registration and use

PDMP

MME Use
Q1/Q2 2021

The CDC recommends that primary care clinicians should reassess evidence of the benefits and risks to the individual when increasing dosage to greater or equal to 50 MME/day and avoid increasing to greater or equal to 90 MME/day when possible due to an increased risk of complications. The CDC also recommends avoiding concurrent benzodiazepine and opioid prescriptions, given the high risk of adverse drug-drug interactions, specifically respiratory depression and death.

CDC checklist for prescribing opioids -
https://www.commerce.alaska.gov/web/portals/5/pub/PDMP_OpiodPrescribeCDC_06.2018.pdf

CDC guidelines for prescribing opioids for chronic pain -
https://www.commerce.alaska.gov/web/portals/5/pub/PDMP_OpiodPrescribeCDCPain_2018.10.pdf

Provider Type	# Providers Prescribing at Least Once	# Providers Who Reviewed 0 Patients	# Providers Prescribing >90MME	# Providers Prescribing >120MME	Dangerous Combo	
					Benzo Opioid	Benzo Opioid Carisoprodol
DEN	333	54% (181)	6% (19)	2% (6)	26% (85)	0
MED	1282	29% (370)	21% (273)	13% (165)	33% (425)	2% (24)
NUR	543	18% (98)	11% (62)	8% (43)	25% (138)	1% (7)
OPT	5	80% (4)	0	0	0	0
PA	347	14% (49)	19% (67)	12% (41)	29% (99)	1% (4)
VET	193	73% (141)	4% (8)	3% (6)	5% (9)	0

INV. REPORT

THE STATE of ALASKA

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Fax: 907.269.8156

MEMORANDUM

DATE: September 09, 2021

TO: Board of Pharmacy

THRU: Greg Francois, Chief Investigator DS SL

FROM: Michael Bowles, Investigator DS MPB

RE: Investigative Report for the September 23, 2021 Meeting

The following information was compiled as an investigative report to the Board for the period of May 07, 2021 thru September 09, 2021; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegals in Anchorage and Juneau, regarding continuing education audits and license action resulting from those matters are covered in this report.

OPEN - 34

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2021-000468	Violation of licensing regulation	Complaint	06/09/2021
2021-000649	Compliance	Complaint	07/29/2021
2020-000530	Violation of licensing regulation	Investigation	04/21/2021
2020-000972	Violation of licensing regulation	Investigation	04/21/2021
2020-000973	Falsified application	Investigation	03/11/2021
2020-001026	Violation of licensing regulation	Investigation	05/04/2021
2020-001084	Violation of licensing regulation	Investigation	05/05/2021
2021-000054	License application problem	Investigation	04/28/2021
2021-000100	License application problem	Investigation	03/23/2021
2021-000110	Violation of licensing regulation	Investigation	04/28/2021

2021-000111	Violation of licensing regulation	Investigation	04/13/2021
2021-000113	License application problem	Investigation	04/28/2021
2021-000232	Violation of licensing regulation	Investigation	05/11/2021

PHARMACIST

2017-000092	Substance abuse	Investigation	02/15/2017
2020-000655	Sexual misconduct	Investigation	07/13/2021
2021-000101	Falsified application	Litigation Initiated	
2021-000532	Falsified application	Litigation Initiated	08/13/2021

PHARMACY

2021-000288	Falsified application	Complaint	05/06/2021
2021-000037	PDMP Violation	Monitor	01/21/2021
2020-000790	Violation of licensing regulation	Investigation	04/21/2021
2021-000163	Violation of licensing regulation	Investigation	04/06/2021
2021-000651	Compliance	Investigation	08/31/2021
2021-000775	Compliance Inspection	Investigation	08/27/2021
2021-000776	Compliance Inspection	Investigation	08/27/2021
2021-000784	Compliance Inspection	Investigation	08/27/2021

PHARMACY TECHNICIAN

2019-000721	Falsified application	Investigation	02/09/2021
2019-000936	Falsified application	Investigation	02/11/2021
2021-000087	Continuing education	Investigation	02/23/2021

REGISTERED NURSE

2021-000380	Drug diversion	Intake	04/30/2021

WHOLESALE DRUG DEALER

2021-000804	Unlicensed practice or activity	Intake	09/08/2021
2021-000733	License application problem	Complaint	08/16/2021
2021-000763	Violation of licensing regulation	Complaint	08/25/2021

2021-000245	Violation of licensing regulation	Investigation	05/11/2021
2021-000497	Violation of licensing regulation	Investigation	08/17/2021

Closed - 30

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2021-000529	Unprofessional conduct	Closed-Intake	07/29/2021	Incomplete Complaint
2021-000648	License application problem	Closed-Intake	08/11/2021	Review Complete
2021-000049	Violation of licensing regulation	Closed-Complaint	06/09/2021	No Action - No Violation
2021-000650	Violation of licensing regulation	Closed-Complaint	08/24/2021	No Action - No Violation
2020-000360	Violation of licensing regulation	Closed-Investigation	06/23/2021	License Action
2020-000602	Violation of licensing regulation	Closed-Investigation	06/23/2021	License Action
2020-000831	Falsified application	Closed-Investigation	05/07/2021	No Action - No Violation
2020-000870	Falsified application	Closed-Investigation	06/21/2021	No Action - No Violation
2020-000886	Violation of licensing regulation	Closed-Investigation	06/23/2021	License Action
2020-001002	Falsified application	Closed-Investigation	06/21/2021	No Action - No Violation
2021-000244	Violation of licensing regulation	Closed-Investigation	05/22/2021	Advisement Letter
PHARMACIST				
2021-000487	PDMP Violation: Failure to Register	Closed-Intake	06/15/2021	License Lapsed - Flagged Do Not Renew
2021-000495	Unprofessional conduct	Closed-Intake	07/21/2021	Incomplete Complaint
2021-000507	PDMP Violation: Failure to Register	Closed-Intake	08/11/2021	Review Complete
2021-000508	PDMP Violation: Failure to Register	Closed-Intake	08/11/2021	Review Complete
2021-000534	Unprofessional conduct	Closed-Intake	07/29/2021	Incomplete Complaint
2021-000535	Unlicensed practice or activity	Closed-Intake	07/29/2021	Incomplete Complaint
2021-000539	PDMP Violation: Failure to Register	Closed-Intake	07/09/2021	License Lapsed - Flagged Do Not Renew
2021-000540	PDMP Violation: Failure to Register	Closed-Intake	07/09/2021	License Lapsed - Flagged Do Not Renew

2021-000164	Unprofessional conduct	Closed-Complaint	05/22/2021	No Action - No Violation
PHARMACY				
2020-001086	Violation of licensing regulation	Closed-Complaint	05/07/2021	No Action - No Violation
2020-000359	Violation of licensing regulation	Closed-Investigation	06/23/2021	License Action
2020-001003	PDMP Violation: Failure to Report	Closed-Investigation	05/21/2021	Advisement Letter
PHARMACY TECHNICIAN				
2021-000085	Continuing education	Closed-Investigation	05/25/2021	License Action
WHOLESALE DRUG DEALER				
2021-000499	License application problem	Closed-Intake	06/21/2021	Review Complete
2021-000652	License application problem	Closed-Intake	07/29/2021	Review Complete
2020-000112	Unlicensed practice or activity	Closed-Investigation	07/08/2021	Advisement Letter
2020-001064	Violation of licensing regulation	Closed-Investigation	06/23/2021	License Action
2021-000469	Violation of licensing regulation	Closed-Investigation	07/29/2021	Advisement Letter
2021-000528	Violation of licensing regulation	Closed-Investigation	08/11/2021	Advisement Letter

END OF REPORT

BOARD BUSINESS

ALASKA BOARD OF PHARMACY
2022 STRATEGIC PLAN

The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

GUIDING PRINCIPLES	GOALS	STRATEGIES
COMMUNICATION	**1.** Engage in effective communication and promote transparency of public information.	**1.1** Improve customer service by providing timely and informative updates to applicants and licensees. **1.2** Encourage appropriate disclosure of information related to licensing and investigative processes. **1.3** Maximize communication channels through the Board of Pharmacy website and List Service. **1.4** Increase collaboration with health care boards and stakeholders to address issues affecting scope of practice and patient care.
ADMINISTRATION	**2.** Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	**2.1** Avoid delays in application processing by maintaining adequate staffing and exploring flexible retention strategies. **2.2** Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process. **2.3** Automate licensure through online applications. **2.4** Exercise fiscal discipline through effective budget management.
LICENSURE	**3.** Ensure competency and qualifications prior to licensure and renewal.	**3.1** Adhere to established licensing standards by reviewing education, experience, and examination requirements. **3.2** Periodically review applications and forms for alignment with existing requirements.
REGULATION & ENFORCEMENT	**4.** Grow the economy while promoting community health and safety.	**4.1** Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety. **4.2** Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP), including collaboration with providers and key stakeholders. **4.3** Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance. **4.4** Establish disciplinary guidelines and conduct random inspections to ensure safety protocols and competencies are met. **4.5** Establish a simple regulatory approach to expand licensure to active duty military personnel and spouse of military personnel. **4.6** Advocate for legislation as the pharmacy profession evolves c new opportunities for improved patient safety arises.

For more information, please visit the following resources:

Board of Pharmacy Homepage: pharmacy.alaska.gov
Prescription Drug Monitoring Program (PDMP): pdmp.alaska.gov

Email: pharmacy@alaska.gov
Phone: 907-465-1073

From: FDA Intergovernmental Affairs
To: Board of Pharmacy (CED sponsored)
Subject: FDA will follow the science on COVID-19 vaccines for young children
Date: Friday, September 10, 2021 5:47:35 AM

If your email program has trouble displaying this email, view as a webpage.

US Food and Drug Administration

Hello,

The FDA Intergovernmental Affairs team would like to bring to your attention that today, **FDA's Acting FDA Commissioner, Janet Woodcock, M.D. and Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Research and Evaluation, issued the following statement.**

FDA will follow the science on COVID-19 vaccines for young children

The following is attributed to Acting FDA Commissioner, Janet Woodcock, M.D. and Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Research and Evaluation

As schools around the country are re-opening for in-person learning and families are returning to their busy school year schedules, we know many parents are anxious about the pandemic and protecting their children. Many parents have questions about COVID-19 and when vaccines will be available for children younger than 12 years of age.

Many of our team at the FDA are parents and grandparents themselves, and our team shares the same concerns as many in our country about protecting our loved ones from COVID-19. We are therefore also eager to see COVID-19 vaccines available for young children. We also know that we all share the interest in making sure this process is done with safety at top of mind. As regulators, we recognize we have an important task ahead of us that will require us to act expeditiously while undertaking an extremely meticulous and thoughtful review once we receive requests to authorize a COVID-19 vaccine for emergency use or submissions for approval of a COVID-19 vaccine for this population.

We know there have been questions and public commentary on the process surrounding vaccines for young children, so we think it's important to share information about the process and the necessary considerations involved to provide greater clarity to the public about this effort.

It's important that the public recognize that, because young children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are completed to evaluate the safety and the immune response to a COVID-19 vaccine in this population. Children are not small adults – and issues that may be addressed in pediatric vaccine trials can include whether there is a need for different doses or different strength formulations of vaccines already used for adults.

Steps the FDA will take to ensure the safety and efficacy of these products for children:

- First, vaccine manufacturers have reported that the necessary clinical trials involving children as participants are currently underway. Some have stated that they are still enrolling, and some are still administering doses or following participants. This process is expected to include a follow-up period of at least about two months, to allow for proper safety monitoring following the administration of vaccine doses for at least half of the clinical trial vaccine recipients.

- Once the manufacturers complete the relevant portion of their clinical trials, they have to complete the analysis of the data from the studies to understand how safe the vaccine is and how well it works in the clinical trial participants. The FDA will work closely with each manufacturer to ensure this data analysis is robust and meets regulatory standards. After manufacturers analyze their clinical trial data, they will compile the information and may request an emergency use authorization (EUA) or submit for approval a biologics license application (BLA), as appropriate, for this young population to the FDA.

- When a completed request for EUA or approval has been received by the FDA, the agency will carefully, thoroughly and independently examine the data to evaluate benefits and risks and be prepared to complete its review as quickly as possible, likely in a matter of weeks rather than months. However, the agency's ability to review these submissions

rapidly will depend in part on the quality and timeliness of the submissions by manufacturers.

Just like every vaccine decision we've made during this pandemic, our evaluation of data on the use of COVID-19 vaccines in children will not cut any corners. Conducting clinical trials to determine an appropriate vaccine dose in children requires additional work over that done in the adult studies, including ensuring that the vaccine dosage and formulation strength used is the appropriate one from the perspective of safety and generating an immune response. Our multi-disciplinary teams of doctors, scientists, statisticians and other experts will thoroughly assess this complex data in making any determination about COVID-19 vaccines in young children. We may also consult with our Vaccines and Related Biological Products Advisory Committee on any questions that warrant a public discussion by external experts. Importantly, once a decision to authorize or approve a vaccine for a younger population has been made, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices will meet to discuss further clinical recommendations.

Parents may be wondering if they can ask their health care providers to go ahead and vaccinate their kids using one of the currently available vaccines outside of the FDA-authorized or approved uses. Parents need to remember that the vaccine doses that are currently being studied in younger children are not necessarily the same vaccine doses that were authorized for individuals 12 years and older or approved for individuals 16 years of age and older—there are different dosing regimens being investigated. It is important for the clinical trials to be completed before vaccinating young kids, so the FDA's team can conduct a thorough evaluation and ensure the data show that the vaccine under consideration is likely to work to prevent COVID-19 in young children and doesn't cause unexpected safety issues separate from those that have already been observed in adolescents and adults.

Just like you, we are eager to see our children and grandchildren vaccinated against COVID-19 as soon as possible. We have to let the science and data guide us. The FDA is working around the clock to support the process for making COVID-19 vaccines available for children. As outlined above, this process is complex and relies on robust manufacturer trials and data, and while we cannot offer a specific date or timeline for when it may be completed for the various manufacturers' vaccine candidates, we can assure the public we are working as expeditiously as possible to meet this critical public health need and we very much hope to have pediatric COVID-19 vaccines available in the coming months.

Until we authorize or approve a vaccine for this younger population, it's especially important that parents and others who interact closely with children under 12 years of age get vaccinated, wear masks, and follow other recommended precautions so that we can protect those who cannot yet protect themselves through vaccination.

You also can find the FDA News Release on our website here. We hope this information is helpful. Please feel free to contact me or FDA's IGA staff at IGA@fda.hhs.gov if you have any questions. Thank you.

Regards,
Michelle

Michelle Adams, MPH
Senior Intergovernmental Affairs Specialist
Intergovernmental Affairs (IGA)
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
Tel: 240.672.6569
Michelle.Adams@fda.hhs.gov

Additional Resources:

- FDA: COVID-19 Vaccines
- FDA Frequently Asked Questions on COVID-19 and Vaccines
- Vaccines and Related Biological Products Advisory Committee | FDA
- Advisory Committee on Immunization Practices (ACIP) | CDC

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS –STATE BOARDS OF PHARMACY

FROM: Josh Bolin, Associate Executive Director, Federal Affairs and Strategy

DATE: September 10, 2021

RE: 9th Amendment to PREP Act Declaration

On September 9, the United States Department of Health and Human Services (HHS) announced the 9th amendment to the COVID-19 PREP Act Declaration. The 9th amendment provides liability immunity to and expands the scope of authority for licensed pharmacists to order and administer COVID-19 therapeutics to populations authorized by the FDA. In addition, the amendment also authorizes pharmacy technicians and pharmacy interns to administer COVID-19 therapeutics when certain criteria are met.

The attached fact sheet contains additional details about the 9th amendment. If you have any questions, please contact me at jbolin@nabp.pharmacy.

cc: NABP Executive Committee
Lemrey "Al" Carter, Executive Director/Secretary

Expanding Access to COVID-19 Therapeutics
HHS PREP Act Declaration: 9th Amendment

COMMITMENT TO ENDING THE COVID-19 PANDEMIC

Throughout the COVID-19 response, the federal government has remained steadfast in providing support to states and territories as part of the whole-of-America approach to fighting the pandemic. The Biden administration remains committed to developing safe and effective therapeutics against the COVID-19 virus and making these drugs accessible across the country.

To support this priority effort, the Department of Health and Human Services (HHS) amended the Public Readiness and Emergency Preparedness (PREP) Act declaration to provide liability protection to **licensed pharmacists, pharmacy technicians**, and **pharmacy interns.**

By expanding PREP Act coverage to include these trained professionals for the administration of covered COVID-19 therapeutics, we are providing a pathway for increased access to COVID-19 therapeutics, particularly in surge states with rising numbers of COVID-19 cases and in rural areas where access to inpatient and outpatient services may be more limited.

COVID-19 PREP ACT DECLARATION

What is a PREP Act Declaration?

The PREP Act allows the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that extends liability protections to entities and individuals who manufacture, distribute, or administer covered medical countermeasures against a public health threat or emergency. In March 2020, the Secretary issued a PREP Act Declaration covering COVID-19 tests, drugs, and vaccines providing liability protections to manufacturers, distributors, SLTTs, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures.

What is the Impact on SLTTs?

The PREP Act and Declaration preempt state requirements, such as more limited licensing or scope of practice requirements, that effectively prohibit a qualified person from prescribing, dispensing, or administering COVID-19 therapeutics. Requirements that do not effectively prohibit qualified persons, such as additional training, are not preempted. Ultimately, states and territories may choose which qualified persons to use for administering COVID-19 therapeutics in their jurisdiction.

For more information on the COVID-19 PREP Act Declaration, please visit: phe.gov

PREP Act Declaration 9th Amendment – Who's Covered?

QUALIFIED PERSONS

The 9th amendment to the COVID-19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID-19 therapeutics to populations authorized by the FDA and for **pharmacy technicians and pharmacy interns** to administer COVID-19 therapeutics to populations authorized by the FDA when the following criteria are meet:

- The COVID-19 therapeutic must be authorized, approved, licensed, or cleared by the FDA.
- In the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be:
  - ordered for subcutaneous, intramuscular, or oral administration and
  - in accordance with the FDA approval, authorization, clearance, or licensing.
- In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be: administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, clearance, or licensing.
- In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician.
- In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include:
  - hands-on injection technique,
  - clinical evaluation of indications and contraindications of COVID-19 therapeutics,
  - the recognition and treatment of emergency reactions to COVID-19 therapeutics, and
  - any additional training required in the FDA approval, authorization, clearance, or licensing.
- The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events.
- The licensed pharmacist, the licensed or registered pharmacy intern, and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.

For more information on the COVID-19 PREP Act Declaration, please visit: phe.gov

From: CDERPASE
To: CDERPASE
Subject: Shelf-Life Extension of Bamlanivimab under the Emergency Use Authorization for Bamlanivimab and Etesevimab Administered Together
Date: Friday, August 20, 2021 3:16:00 PM
Attachments: image003.png

The Health and Human Services' Office of the Assistant Secretary for Preparedness and Response and the Food and Drug Administration are announcing the authorization of an extension to the shelf-life from 12 months to 18 months for the refrigerated Eli Lilly monoclonal antibody, bamlanivimab, which is currently authorized for emergency use only when administered together with etesevimab. As a result of this extension, unopened vials of bamlanivimab injection, 700 mg/20 mL, may be stored for an additional 6 months from the labeled date of expiry and should be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F). This extension applies to all unopened vials of bamlanivimab that have been held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 094 for bamlanivimab and etesevimab, administered together.

For more information, please see: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/default.aspx

Professional Affairs and Stakeholder Engagement | Office of Center Director
Center for Drug Evaluation and Research |Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

From: FDA Intergovernmental Affairs
To: Board of Pharmacy (CED sponsored)
Subject: FDA Intergovernmental Affairs Team: COVID-19 Update and Weekly Digest for the Week of August 16, 2021
Date: Friday, August 20, 2021 12:56:37 PM

FDA

Intergovernmental Affairs

Weekly Digest for the Week of August 16, 2021

Good afternoon. The FDA Intergovernmental Affairs (IGA) team would like to bring to your attention the following announcements the Agency made during the week of August 16, 2021. If you have any questions on the below announcements, please reach out to us at IGA@fda.hhs.gov.

FDA Warnings and Recalls

- **FDA is informing health care providers, health care facility risk managers, and procurement staff to immediately stop using and discard all ultrasound gels and lotions manufactured by Eco-Med Pharmaceutical, Inc., due to risk of bacterial contamination with *Burkholderia cepacia* complex (Bcc).** Products manufactured by Eco-Med are distributed by a number of distributors under various product names, including MediChoice Ultrasound Gel distributed by both Owens & Minor and Mac Medical Supply Co., Inc. (See full list here).

Eco-Med initiated a voluntary recall on Aug. 4, 2021, to stop use of EcoGel 200 Ultrasound Gel due to risk of bacterial contamination. However, the FDA has determined that **all** ultrasound gels and lotions manufactured by Eco-Med are at risk for bacterial contamination. The FDA's determination is based on concerns that the company did not complete its investigation of the issues, the root cause and extent of bacterial contamination was not identified, and multiple products could be affected by manufacturing issues associated with the company's ultrasound gel (such as inappropriate testing of finished product, inadequate testing of raw materials, and a lack of environmental controls). Eco-Med has shut down all operations and is no longer manufacturing or distributing any products. Additional information can be found here.

- On August 11, 2021, **FDA announced that there are new cases identified in its *Salmonella* Weltevreden investigation, however the shrimp are outside of the recall linked to illnesses.** FDA, along with CDC and state and local partners, investigated a multistate outbreak of *Salmonella* Weltevreden infections linked to the consumption of frozen cooked shrimp manufactured by Avanti Frozen Foods of India. On July 21, 2021, CDC announced that this outbreak was over. **Since July 21, 2021, additional cases have been identified in this outbreak**. At least one ill person consumed shrimp that are not a part of the current recall. **Due to this new information, on August 10, 2021 the FDA asked the firm to expand their current recall to prevent additional illnesses**. As of August 11, 2021, the firm has not initiated an expanded recall. FDA is continuing discussions with the firm and will provide more updates when available. The current recall includes the following brands: CENSEA, CHICKEN OF THE SEA, HONEST CATCH, CWNO, HANNAFORD, WATERFRONT BISTRO, OPEN ACRES, 265, and MEIJER. Please check the recall announcement for full product descriptions.

COVID-19 Updates

- As part of the FDA's effort to protect consumers, on August 19, 2021, **the Agency issued a warning letter jointly with the Federal Trade Commission to Mahita, LLC dba PushMyCart for selling unapproved products with unproven COVID-19 claims.** Consumers concerned about COVID-19 should consult with their health care provider.

- On August 18, 2021, **public health and medical experts from the U.S. Department of Health and Human Services (HHS) released a statement on the Administration's plan for COVID-19 booster shots for the American people.** The statement can be found here.

- On August 12, 2021, **FDA amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.** People who are immunocompromised in a manner similar to those who have undergone solid organ transplantation have a reduced ability to fight infections and other diseases,

and they are especially vulnerable to infections, including COVID-19. FDA evaluated information on the use of a third dose of the Pfizer-BioNTech or Moderna Vaccines in these individuals and determined that the administration of third vaccine doses may increase protection in this population. **Yesterday's action does not apply to people who are not immunocompromised.** You can find the FDA News Release on our website here.

- On August 13, 2021, **Assistant Secretary for Health for the U.S. Department of Health and Human Services (HHS), Rachel L. Levine, M.D., and Peter Marks, M.D., Ph.D., Director, FDA Center for Biologics Evaluation and Research, participated in a meeting with stakeholders to discuss vaccine updates for younger children and adolescents.** You can view the meeting here.

- A new FDA Consumer Update highlights 5 Things to Know about COVID-19 Vaccination for Adolescents. The FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine for emergency use to prevent COVID-19 in people 12 and older. The CDC recommends COVID-19 vaccination for everyone 12 and older.

- FDA's vaccine expert, Dr. Peter Marks, participated in the HHS Ask An Expert video series to answer some of your most frequently asked questions about COVID-19 vaccination.

- The Washington Post: **Interview: Dr. Peter Marks discusses the process for full approval, also known as licensing, of COVID-19 vaccines.**

- Testing updates

    - As of today, 402 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 282 molecular tests and sample collection devices, 87 antibody and other immune response tests and 33 antigen tests. There are 56 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, six antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests.

    - The FDA has authorized 13 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 610 revisions to EUA authorizations.

REMINDERS:

- FDA holds weekly **Virtual Town Halls on COVID Diagnostics, every Wednesday** – from 12:15 to 1:15 pm ET. For more information, click here.

- **FDA hosts regular webinars to share information and answer your questions about respirators and other personal protective equipment (PPE).** For more information, click here.

RESOURCES:

- FDA's Office of Minority Health and Health Equity (OMHHE) has **released a Health Equity Forum Podcast - A conversation with the FDA Chief Scientist: Learn about the Emergency Use Authorization (EUA) Process.**

- **FDA's Coronavirus Disease 2019 (COVID-19)** webpage provides the latest news and information.

- FDA's **COVID-19 Vaccines webpage** at www.fda.gov/covid19vaccines highlight new information as it becomes available

- FDA's webpage - **A Closer Look at COVID-19 Diagnostic Testing** - provides health care providers and other public health professionals, including those who might purchase COVID-19 tests, with more technical information and resources.

- **Coronavirus Treatment Acceleration Program (CTAP)** information can be found here.

Drugs and Biologics

- On August 9, 2021, **FDA announced in the Federal Register that is extending until Oct. 27, 2022, the period for states to consider and sign the compounding memorandum of understanding (MOU) before FDA intends to begin enforcing the statutory five percent limit on distribution of compounded human drug products out of state, in states that have not signed the MOU.** Read more here.

Devices

- **FDA announced a virtual public workshop entitled "Spinal Device Clinical Review,"** being held on September 17, 2021. This workshop is intended to enhance public understanding of FDA's approach to clinical review of spinal devices falling under 21 CFR Part 888. The purpose of the workshop is to provide information to our stakeholders, including members of the orthopedic community, device manufacturers, regulatory affairs professionals, clinicians, patients and the general public, regarding FDA regulations, guidances and regulatory pathways related to spinal device clinical review. For more information, including registration details, click here.

Food and Food Safety

- FDA announced on July 29, 2021, that it will **host a virtual summit October 19-21, 2021, to convene industry and consumer experts, government officials, stakeholders and other interested parties for a discussion and exchange of perspectives about the safety of human and animal foods produced, manufactured, sold, and delivered**

directly to consumers through e-commerce. Summit participants will discuss the regulatory framework that apply to these foods and ways to strengthen food safety. More specifics, including information on how to register for the summit will follow in the Federal Register and on the FDA website.

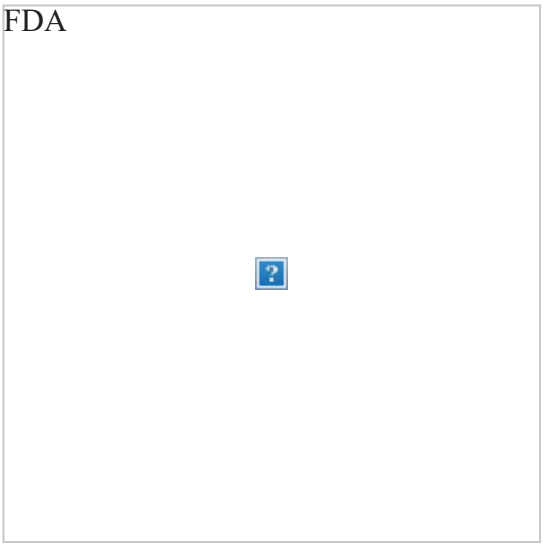
Veterinary Medicine

- **FDA has issued a corporate-wide warning letter to Midwestern Pet Foods, Inc. after inspections of its manufacturing sites revealed apparent violations of the Federal Food, Drug, and Cosmetic Act that were shared across the sites. These conditions likely contributed to the illness or death of hundreds of dogs.** The FDA In Brief and additional information, can be found here.

Subscribe to FDA email notifications here

FDA website for Federal, State, Local, Tribal, and Territorial Officials here

From: FDA Intergovernmental Affairs
To: Board of Pharmacy (CED sponsored)
Subject: FDA Intergovernmental Affairs Team: COVID-19 Update and Weekly Digest for the Week of August 30, 2021
Date: Friday, September 3, 2021 1:06:53 PM



Intergovernmental Affairs

Weekly Digest for the Week of August 30, 2021

Good afternoon. The FDA Intergovernmental Affairs (IGA) team would like to bring to your attention the following announcements the Agency made during the week of August 30, 2021. If you have any questions on the below announcements, please reach out to us at IGA@fda.hhs.gov.

FDA Warnings and Recalls

- On August 30, 2021, **FDA issued a letter to veterinarians and retailers asking for assistance in sharing important safety information with consumers about the dangerous misuse of animal ivermectin to prevent or treat COVID-19 in people.** As noted in many recent news stories and in a Health Alert from the U.S. Centers for Disease Control and Prevention, poison control centers across the U.S. are seeing a sharp spike in reports of people suffering adverse health effects after taking animal ivermectin. People are purchasing various highly concentrated animal ivermectin drug formulations such as "pour-on," injectable, paste, and "drench" that are intended for

horses, cattle, and sheep, and taking these drugs has made some people very sick. Even if animal drugs have the same active ingredient as an approved human drug, animal drugs have not been evaluated for safety or effectiveness in humans. Treating human medical conditions with veterinary drugs can be very dangerous.

COVID-19 Updates

- **FDA has announced a virtual meeting of its Vaccines and Related Biological Products Advisory Committee to discuss the matter of additional doses of COVID-19 vaccines and specifically to discuss the Pfizer-BioNTech supplemental Biologics License Application for administration of a third ("booster") dose of Comirnaty (COVID-19 Vaccine, mRNA) in individuals 16 years of age and older. The meeting will be held on Sept. 17, 2021, from 8:30 a.m. to 3:45 p.m. EST.** The FDA intends to make background material available to the public, including the meeting agenda and committee roster, no later than two business days before the meeting. **The FDA intends to livestream the VRBPAC meeting on the agency's YouTube channel; the meeting will also be webcast from the FDA website.** You can find the **FDA In Brief: FDA to Hold Advisory Committee Meeting to Discuss Pfizer-BioNTech's Application for COVID-19 Booster** on our website here. You can access the **Vaccines and Related Biological Products Advisory Committee September 17, 2021 Meeting Announcement** webpage here.

- On August 27, 2021, **the FDA made changes to the authorized use of the monoclonal antibodies bamlanivimab and etesevimab, administered together. The Emergency Use Authorization now authorizes the use of bamlanivimab and etesevimab, administered together, only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%.** FDA has posted a list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together are currently authorized, and a list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together, are not currently authorized, and will periodically update both lists as new data and information becomes available.

- On August 23, 2021, **FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older.** The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals. Additional information can be found here.

- **An FDA Consumer Update highlights 5 Things to Know about COVID-19 Vaccination for Adolescents.** The FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine for emergency use to prevent COVID-19 in people 12 and older. The CDC recommends COVID-19 vaccination for everyone 12 and older.

- **FDA's vaccine expert, Dr. Peter Marks, participated in the HHS Ask An Expert video series** to answer some of your most frequently asked questions about COVID-19 vaccination.

- The Washington Post: **Interview: Dr. Peter Marks discusses the process for full approval, also known as licensing, of COVID-19 vaccines.**

- Testing updates

    - As of August 31, 2021, 409 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 287 molecular tests and sample collection devices, 88 antibody and other immune response tests and 34 antigen tests. There are 61 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, seven antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests.

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- **FDA hosts regular webinars to share information and answer your questions about respirators and other personal protective equipment (PPE).** For more information, click here.

RESOURCES:

- **Translations of the COVID-19 vaccines emergency use authorization (EUA) fact sheets for recipients and caregivers are available in 27 languages, including Farsi, Navajo, and Spanish.** You can find translated COVID-19 vaccine fact sheets here:

    - **Pfizer-BioNTech** COVID-19 Vaccine

    - **Moderna** COVID-19 Vaccine

    - **Janssen** COVID-19 Vaccine

- FDA's Office of Minority Health and Health Equity (OMHHE) has **released a Health Equity Forum Podcast - A conversation with the FDA Chief Scientist: Learn about the Emergency Use Authorization (EUA) Process.**

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Food and Food Safety

- FDA **announced it has upgraded its Center for Food Safety and Applied Nutrition (CFSAN) Education Resource Library to allow users to locate information faster and with more ease** on September 1, 2021. The online library provides consumers, industry, educators, dietitians, health professionals, and regulators with a catalog of more than 350 printable educational materials and videos on topics related to food safety, nutrition (including labeling and dietary supplements), agricultural biotechnology, and cosmetics. Design upgrades to the library include a new and improved cloud-based interface and key word search function. Find additional information here.

- On September 3, 2021, **FDA issued a Federal Register Notice to formally announce a three-day public meeting to discuss the safety of foods sold online and delivered**

directly to consumers. The FDA New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers will take place virtually October 19-21, 2021. The summit is designed to help the agency improve its understanding of how human and animal foods are sold through Business to Consumer (or B2C for short) e-commerce models across the U.S. and globally. You can read more about the meeting and registration, here.

Tobacco

- **FDA issued marketing denial orders (MDOs) for approximately 300,000 flavored electronic nicotine delivery system (ENDS) products to an additional 31 companies.** FDA continues to make substantial progress reviewing the unprecedented number of applications received by the Sept. 9, 2020, court-ordered deadline for submission of premarket applications for deemed new tobacco products. The MDOs announced today follow the previously announced first MDOs that FDA issued for companies whose applications reached the substantive scientific review portion of premarket review. The aggregate information on these actions will be provided within our regular updates on the Tobacco Product Applications: Metrics and Reporting page.

- On around September 1, 2021, **FDA/CTP will post two new Tobacco Compliance webinars**:
    - **"What a Brick and Mortar Tobacco Retailer Should Do After Receiving a Warning Letter."** This webinar will provide retailers with information about what to do after they've received a Warning Letter.

    - **"Tobacco 21: Update for Retailers."** The webinar provides up-to-date information about T21, how retailers (including online retailers) can comply with T21 requirements, and additional resources for tobacco retailers.

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Annual Report

Fiscal Year 2021

Board of Pharmacy

Department of Commerce, Community and Economic Development

Division of Corporations, Business and Professional Licensing

This annual performance report is presented in accordance with Alaska statute AS 08.01.070(10).

Its purpose is to report the accomplishments, activities, and the past and present needs of the licensing program.

Board of Pharmacy
FY 2021 Annual Report

Table of Contents

Board of Pharmacy
FY 2021 Annual Report

Identification of the Board

Board Member	Duty Station	Date Appointed	Term Expires
Richard Holt, PharmD, MBA Chair	Eagle River, AK	Mar 01, 2020	Mar 01, 2024
Leif Holm, PharmD Vice Chair	North Pole, AK	Mar 01, 2015	Mar 01, 2023
Lana Bell, RPh Secretary	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
James Henderson, RPh	Soldotna, AK	Mar 01, 2017	Mar 01, 2025
Justin Ruffridge, PharmD	Anchorage, AK	Mar 01, 2020	Mar 01, 2024
Sharon Long Public Member	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
Tammy Lindemuth Public Member	Anchorage, AK	Mar 01, 2018	Mar 01, 2025

Board of Pharmacy
FY 2021 Annual Report

Identification of Staff

Laura Carrillo, MPH – Executive Administrator
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
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Lisa Sherrell – Prescription Drug Monitoring Program Manager (since January 2020)
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Michael Bowles – Investigator III (since February, 2021)
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Heather Noe – Licensing Examiner (since January 2020)
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Division of Corporations, Business and Professional Licensing
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Bethany Carlile – Licensing Examiner (since November 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
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Juneau, Alaska 99811-0806
(907) 465-2550

Board of Pharmacy
FY 2021 Annual Report

Narrative Statement

The Alaska Board of Pharmacy "the board" endeavors to promote, preserve, and protect the public health, safety, and welfare of the public by and through the effective control and regulation of the practice of pharmacy. During FY2021, the board continued its efforts to support the pharmaceutical supply chain, marking one year of expanding its regulatory oversight of non-resident wholesale drug distributors, outsourcing facilities, and third-party logistics providers. The board of pharmacy continued to regulate in-state pharmacies, out-of-state pharmacies, remote pharmacies, drug rooms, in-state wholesale drug distributors, pharmacists, pharmacist interns, and pharmacy technicians. In all, the board added over 1,250 new licensees to its user base in FY2021, bringing the total number of regulated individuals and entities to approximately 4,700. The board also continued to regulate shared pharmacy services and telepharmacy systems, review and approve collaborative practice agreements with practitioners, and administer the state's controlled substance prescription database, the Prescription Drug Monitoring Program (PDMP).

Through its comprehensive emergency response, the board continued to support the state's strategic health response, balance healthcare delivery sites, and aid in the scaling up of vital pharmacy support services during this unprecedented pandemic. The board swiftly implemented emergency preparedness regulations in FY2020, making these permanent in July FY2021. These regulations reduce barriers to licensure and bridge accessibility gaps to critical patient services by relaxing license application requirements and allowing for the delivery of medications by support staff without the need to obtain licensure. By mid-FY2021, the board expanded its existing emergency pharmacist permit to include pharmacist interns and pharmacy technicians, expediting priority license applications and increasing pharmacy personnel coverage across the state. The board also created a new courtesy license category to allow pharmacy personnel to provide COVID-19 vaccines. These collective efforts, which align with the U.S. Department of Health and Human Services' (HHS) Public Readiness and Emergency Preparedness Act (PREP Act) – helped to elevate the state's vaccine distribution capacity and alleviate immunization strains bottlenecked by previous limitations on certain personnel authorized to provide this service.

Legislatively, the board testified in support of the Alaska Pharmacists Association's (AKPhA) pharmacist mobilization bill, HB145, which highlights the reality that pharmacists are uniquely positioned and qualified to assist with the scaling up of patient care and in filling critical health management gaps. The bill introduced language to recognize pharmacists as providers for the purpose of meeting insurance reimbursement eligibility and to clarify that prescribing for general wellness is already within pharmacists' scope of practice, particularly for those working in institutional and primary care settings. Additionally, the board supported the Nurse Licensure Compact bill and took a neutral position on the Board of Veterinary Examiner's PDMP exemption bill.

The board is statutorily required to meet at least three (3) times per year either in person or telephonically. In FY2021, the board held five (5) regular board meetings via video conference, realizing an estimated $8,000 - $15,000 in travel savings than if the meetings were held in person. Through regulatory subcommittees, the board continued its efforts to reduce regulatory barriers, identify outdated regulations, and assess for administrative efficiencies. In its ongoing effort to adhere to its mission, the board also approved its 2021 Strategic Plan, which includes goals and strategies around the areas of communication, administration, licensure, and regulation and enforcement.

The Controlled Substances Advisory Subcommittee (CSAC) continues to be led by the Board of Pharmacy's chair or chair's delegate. In FY2021, the CSAC continued discussing recently emerging substances of abuse, including kratom and gabapentin. This year, the CSAC decided to put forward a recommendation that Governor Dunleavy schedule kratom as a state-controlled substance to enable prosecution authority and to reduce the diversion and misuse of this substance.

The Board of Pharmacy also maintains its membership with the National Association of Boards of Pharmacy (NABP) and the National Association of Controlled Substance Authorities (NASCA), which provides the board with industry support and access to national resources, many of which provides administrative efficiency and supports the board in avoiding redundant services and lowering costs to the State, prospective applicants, and licensees. Through its membership with the NABP and at no additional cost, the board of pharmacy is able to delegate administration of its state jurisprudence exam for pharmacist licensure and reporting of disciplinary actions to the association. The NABP also provides an ePortal service for transfer of national examination scores and state licenses, a continuing education monitoring service, and intrastate and interstate datasharing hubs to facilitate exchange of data through the PDMP. Through its membership with NASCA, the board has access to discussion forums and comprehensive state information to assist in curtailing the abuse, misuse, and diversion of controlled substances.

A valuable longstanding relationship also exists with the Board of Pharmacy and the Alaska Pharmacists Association (AKPhA). In FY2021, the AKPhA collaborated with the Board of Pharmacy to draft legislation for expanding pharmacist practice authority and sought support from other provider types to strengthen the need for this legislation. Through HB 145, the bill proposed to update pharmacists' existing ability to independently prescribe certain medications, such as vaccines and opioid overdose drugs. The bill also proposed adding language to clarify services pharmacists are authorized to perform independent of and within a collaborative practice agreement relationship with a prescribing practitioner, including providing services for general health and wellness, disease prevention, and optimization of medication therapy. Notably, the bill also sought to make pharmacists eligible for reimbursement for these services under title 21. Though the bill ultimately did not pass this year, the board will continue to support the AKPhA in this legislative effort for the second session.

Board of Pharmacy
Fiscal Year 2021 Annual Report

Budget Recommendations for FY 2022

The Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
September 23 – 24, 2021	Anchorage	3	1
☒ Airfare:			$2,000.00
☒ Hotel:			$1,200.00
☒ Ground:			$100.00
☒ Other: M&IE			$350.00
Total Estimated Cost:			**$3,650.00**

Board Meeting Date	Location	# Board	# Staff
November 18-19, 2021	Anchorage	3	1
☒ Airfare:			$2,000.00
☒ Hotel:			$1,200.00
☒ Ground:			$100.00
☒ Other: M&IE			$350.00
Total Estimated Cost:			**$3,650.00**

Board Meeting Date	Location	# Board	# Staff
February 17-18, 2021	Juneau	6	0
☒ Airfare:			$4,000.00
☒ Hotel:			$2,400.00
☒ Ground:			$0.00
☒ Other: M&IE			$600.00
Total Estimated Cost:			**$7,000.00**

Budget Recommendations for FY 2022 (continued)

Travel Required to Perform Examinations

☒ Not applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Conference:	$0.00
☐ Other:	$0.00
Describe "Other" (break out all sections):	
Total Estimated Cost:	**$0.00**

Out-of-State Meetings and Additional In-State Travel (Rank in order of importance)

☒ #1 Rank in Importance or ☐ Not Applicable

Date	Location	# Board	# Staff
August 29 – September 1, 2021	Carefree, AZ	1	1

Description of meeting and its role in supporting the mission of the Board:

This is an NABP District 6 – 8 meeting (Alaska is in district 7). This is a unique opportunity to roundtable with district members on matters affecting today's pharmacy practice and an opportunity to engage in proactive discussions for tomorrow's pharmacists. Attendees will propose and resolve resolutions in an ongoing effort to support the practice of pharmacy.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$500.00	$0.00	$0.00	$500.00
☒ Hotel:	$2,500.00	$0.00	$0.00	$2,500.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$1,080.00	$0.00	$0.00	$1,080.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$4,180.00**	**$0.00**	**$0.00**	**$4,180.00**

Out-of-State Meetings and Additional In-State Travel

#2 Rank in Importance

Date	Location	# Board	# Staff
May 19 - 22, 2021	Phoenix, AZ	1	1

Description of meeting and its role in supporting the mission of the Board:

118th Annual Meeting of the National Association of Boards of Pharmacy (NABP) – State boards, regulators, and stakeholders gain a deeper understanding of how NABP and the pharmacy regulatory boards work together to protect public health. Attendees have the opportunity to network and participate in business sessions to keep abreast of the salient issues affecting pharmacy practice and regulation.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$1,500.00	$0.00	$0.00	$1,500.00
☒ Hotel:	$2,500.00	$0.00	$0.00	$2,500.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☒ Conference:	$400.00	$0.00	$0.00	$400.00
☒ Other	$1,080.00	$0.00	$0.00	$1,080.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$5,580.00**	**$0.00**	**$0.00**	**$5,580.00**

Out-of-State Meetings and Additional In-State Travel

#3 Rank in Importance

Date	Location	# Board	# Staff
April 18 - 21, 2022	Atlanta, GA	1	2

Description of meeting and its role in supporting the mission of the Board:

National Rx Abuse and Heroin Summit – This conference supports the state's opioid response and the board's efforts to effectively administer the state's PDMP. Federal grant funds will be used to send 2 staff members to this conference to attend the PDMP track. License fees will be used to send 1 board member to attend the regulatory, policy, clinical, and/or law enforcement tracks. The below cost reflects travel for 1 board member.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$1,700.00	$0.00	$0.00	$1,700.00
☒ Hotel:	$750.00	$0.00	$0.00	$750.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☒ Conference:	$750.00	$0.00	$0.00	$750.00
☒ Other	$170.00	$0.00	$0.00	$170.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$3,470.00**	**$0.00**	**$0.00**	**$3,470.00**

Out-of-State Meetings and Additional In-State Travel

#4 Rank in Importance

Date	Location	# Board	# Staff
August 9 – September 10, 2021	Virtual	1	1

Description of meeting and its role in supporting the mission of the Board:

MPJE State-Specific Review – this is an opportunity for member boards to participate in review of current exam items to ensure the most valid and relevant questions are reflected in the Multi-State Jurisprudence Exam (MPJE), which is administered by the NABP. This exam is integral to assessing competency for licensure as a pharmacist. Participation in this workshop also allows for selection of new items for pre-testing, which is integral to the validity of MPJEs.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#5 Rank in Importance

Date	Location	# Board	# Staff
June 16 – 17, 2021	Virtual	2	0

Description of meeting and its role in supporting the mission of the Board:

Compounding Pharmacy Compliance - The board, through their compounding subcommittee, has been working on advancing their compounding regulations over the last few years. This conference is an opportunity to netword with expertens in the compounding industry, analyze evolving regulations, strengthen compounding systems and processes, and gain insight into techniques to ensure accuracy and sterility. The overarching goal is patient safety.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☒ Conference:	$2,400.00	$0.00	$0.00	$2,400.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$2,400.00**	**$0.00**	**$0.00**	**$2,400.00**

Out-of-State Meetings and Additional In-State Travel

#6 Rank in Importance

Date	Location	# Board	# Staff
TBD	Multiple	1	0

Description of meeting and its role in supporting the mission of the Board:

Investigator-performed pharmacy inspections throughout the state to ensure compliance with applicable regulations and safety standards.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$4,000.00	$0.00	$0.00	$4,000.00
☒ Hotel:	$1,000.00	$0.00	$0.00	$1,000.00
☒ Ground:	$300.00	$0.00	$0.00	$300.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$500.00	$0.00	$0.00	$500.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$5,800.00**	**$0.00**	**$0.00**	**$5,800.00**

Out-of-State Meetings and Additional In-State Travel

#7 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Budget Recommendations for FY 2022 (continued)

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☒ Other

Product or Service	Provider	Cost Per Event
Fingerprint processing fee		$75.00

Description of item and its role in supporting the mission of the Board:

The Board of Pharmacy is currently absorbing costs to process fingerprint cards. So far, the board has issued over 850 fingerprint-required licenses, an estimated cost of $64,000.

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

Budget Recommendations for FY 2022 (continued)

Other Items with a Fiscal Impact

Cost Per Event: **$0.00**

☐ **Not Applicable**

Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

Cost Per Event: **$0.00**

☐ **Not Applicable**

Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Summary of FY 2022 Fiscal Requests

Board Meetings and Teleconferences:	$14,300.00
Travel for Exams:	$0.00
Out-of-State and Additional In-State Travel:	$21,430.00
Dues, Memberships, Resources, Training:	$75.00
Total Potential Third-Party Offsets:	–$0.00
Other:	$0.00
Total Requested:	**$35,805.00**

Legislation Recommendations Proposed Legislation for FY 2022

☐ **No Recommendations**
The Board has no recommendations for proposed legislation at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed legislation:

The Alaska Pharmacists Association (AKPhA) introduced legislative changes through HB 145 in FY2021 that overlap with changes the Board of Pharmacy previously identified in its FY2020 legislative recommendations. Though the bill did not pass, it is anticipated the following amendments will be reflected in rollover legislation in the second session:

- Removing "dosage form" from the definition of "equivalent drug product" in AS 08.80.480.
- Clarifying pharmacists' ability to independently prescribe and administer vaccines and emergency medications under AS 08.80.168, and expand their ability to provide independent treatment to other conditions as appropriate
- Allowing pharmacist interns and pharmacy technicians, as supervised by a pharmacist, to prescribe vaccines and emergency medications under AS 08.80.168, and expand their ability to provide supervised treatment to other conditions as appropriate
- Allowing other pharmacy personnel, as delegated by the pharmacist, to disclose prescription prices, including less costly alternatives per AS 08.80.297

Additionally, the Board of Pharmacy will support legislation to regulate the practice of white bagging and brown bagging. During it's May 20-21, 2021 meeting, the AKPhA presented its official letter to the board outlining concerns with white bagging and its negative financial affect on facilities, the risks it poses to the FDA's Drug Supply Chain Security Act (DSCSA), and the complex inventory management it imposes on pharmacy staff.

A summary of the Board of Pharmacy's legislative recommendations include:

Statutory area	Summary of Change	Citation
Annual report	Remove annual report requirement; allow updates to be provided at the time of renewal	AS 80.80.158(b)
Moral character	Remove moral character requirement from applications for pharmacists via examination, reciprocity,	AS 08.80.110(2), AS 08.80.145(3)
Registration of pharmacies	Repeal registration and introduce licensure category	AS 08.80.158
Requirements for non-resident pharmacies	Include devices, require licensure	AS 08.80.159
Licenses not affected	Drug dispensing machines	AS 08.80.400
Prohibited terms	Add "apothecary"	AS 08.80.420

Legislation Recommendations Proposed Legislation for FY 2022 *(Continued)*

The Board of Pharmacy's proposed changes are as follows:

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall
(1) be fluent in the reading, writing, and speaking of the English language;
~~(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;~~
(3) be a graduate of a college in a degree program approved by the board;
(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person
~~(1)~~ submits a written application to the board on a form required by the board;
(2) is at least 18 years of age;
~~(3) is of good moral character;~~
(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
(5) has engaged in the practice of pharmacy for at least one year ~~or has met the internship requirements of this state~~ within the one-year period immediately before applying for a license under this section;
(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;
(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and (8) pays all required fees.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:
(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer; (4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) ~~registration or~~ licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF~~ DRUGS ~~VACCINES AND RELATED EMERGENCY MEDICATIONS.~~
(a) A pharmacist may independently prescribe
(1) and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(2) and dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
(3) and dispense dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
(4) and dispense epinephrine auto-injectors;
(5) and dispense drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:
(A) do not require a new diagnosis;
(B) are minor and generally self-limiting;
(C) have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
(D) in the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
(6) In this section,
(1) "opioid overdose drug" has the meaning given in AS 17.20.085;
(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

(b) The board shall not adopt any regulations authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.
(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.
(c) In this section, "regularly" means to dispense more than a 3-day supply to a patient.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," "apothecary", or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Regulation Recommendations Proposed Legislation for FY 2022

☐ **No Recommendations**
The Board has no recommendations for proposed regulations at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed regulations:

12 AAC 52.020. ~~FACILITY~~ PHARMACY LICENSE. (repeal & readopt)

(a) An applicant for a ~~facility~~ **pharmacy** license shall submit
(1) the **applicable** fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) **an attestation that** within 14 days after commencement of business, a ~~completed~~ self-inspection ~~of the premises questionnaire~~ on a form provided by the department **will be completed. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed;** and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.
(f) a pharmacy that has changed its name, ownership, or physical address shall apply for a new and separate license in accordance with this section.

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (repeal)

(a) ~~The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall~~
~~(1) submit a new, completed application for a pharmacy license on a form provided by the department; and~~
~~(2) pay the duplicate license fees required in 12 AAC 02.105;~~
~~(3) repealed 1/17/2007.~~
~~(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.~~

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (repeal)

~~(a) Repealed 1/17/2007.~~
~~(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.~~

Regulation Recommendations Proposed Legislation for FY 2022 *(Continued)*

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (amend)

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

~~(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or~~

(B) a ~~certified~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~and~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080 ~~from the agency where the hours of internship or experience were completed~~;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (amend)

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(2) pays the ~~application fee and the out-of-state pharmacy registration~~ **applicable** fee**s** established in 12 AAC 02.310;

(3) submits a ~~certified true~~ copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an **attestation that an** inspection report or self-inspection report **was** completed within the last two years **or since the last time the registration was initially issued**. **A self-inspection must be retained, and made available upon request, for the duration of the licensing period in which it was completed.**

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (amend)

~~(a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.~~

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department.

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;
(2) the applicable fees established in 12 AAC 02.310;
(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;
(4) either

~~(~~**~~(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or~~**

(B) a ~~certified~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~and~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (amend)

~~(a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements set out in (c) of this section has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity.~~

~~(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.~~

(c) An applicant for licensure under this section must submit to the department
(1) a complete, notarized application on a form provided by the department;
(2) the applicable fees established in 12 AAC 02.310;
(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;
(4) either

~~(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or~~

(B) a ~~certified~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~and~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;
(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080.~~; the verification must be sent directly to the department from the agency where the hours of internship~~ **or**

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) ~~verification that the applicant is currently licensed as a pharmacist in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements~~;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy. **The license by which the applicant is seeking reciprocity from must be in good standing**;

(10) verification of the present status of the applicant's **pharmacist** license ~~in each licensing~~ **from the** jurisdiction where the applicant **is reciprocating**. ~~holds, or has ever held, a license as a pharmacist.~~

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (repeal & re-adopt)

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the **applicable** ~~application fee and the pharmacist intern license~~ fee**s** established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

~~(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act);~~ and

~~(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.~~

B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

~~(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act);~~ and

~~(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.~~. (repeal and re-adopt)

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (repeal and re-adopt)

(a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.
(c) Repealed 4/16/2016.
~~(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.~~

12 AAC 52.200. PHARMACIST-IN-CHARGE. (amend)

(b) The responsibilities of the pharmacist-in-charge include
(1) compliance with all laws and regulations governing the activities of the pharmacy;
(2) training of all pharmacy personnel;
(3) ~~establishing~~ **ensuring adequate** policies and procedures **are in place** for pharmacy operations~~;~~
(4) maintaining required records;
(5) storage of all materials, including drugs and chemicals;
(6) ~~establishing~~ **ensuring** ~~and maintaining~~ effective controls against theft or diversion of prescription drugs; and
(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.
(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department or ~~and paying the applicable fees established in 12 AAC 02.105(3).~~
(d) A pharmacist-in-charge may practice in more than one pharmacy location and may be designated as the pharmacist-in-charge of multiple pharmacies simultaneously.

12 AAC 52.300. LICENSE RENEWAL. (repeal and re-adopt)

(a) Pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider** and drug room licenses expire on June 30 of even-numbered years.
(b) An applicant for renewal of a pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider** or drug room license shall submit **on or before the license expiration date**
(1) a completed renewal application **on a form provided by the department;**
(2) the license renewal fees required in 12 AAC 02.310; and
(3) **an attestation** ~~completed~~ **that a** self-inspection of the premises **using the** ~~questionnaire~~ ~~on a~~ form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed.**
(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date
(1) a completed renewal application **on a form provided by the department; and**
(2) the license renewal fees required in 12 AAC 02.310; ~~and~~
~~(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;~~
(4) repealed 4/3/2020.
(d) A pharmacy that has changed its name, physical address, or ownership since the date it was first issued or last renewed is not eligible for renewal.
(e) A wholesale drug distributor that has changed its name, physical address, ownership, or facility manager is not eligible for renewal if the change occurred 30-days after the date a renewal application is submitted to the board.
(f) An outsourcing facility or third-party logistics provider that has changed its name, physical address, ownership, or facility manager is not eligible for renewal.

Regulation Recommendations Proposed Legislation for FY 2022 (Continued)

The Board of Pharmacy intends to make additional changes to the following regulations:

- 12 AAC 52.610 – Wholesale drug distributor license
- 12 AAC 52.696 – Outsourcing facilities
- 12 AAC 52.697 – Third-party logistics provider
- 12 AAC 52.585 – Mandatory patient counseling
- 12 AAC 52.460 – Prescription drug order information
- 12 AAC 52.415 – Automated dispensing kiosk (new)
- 12 AAC 52.420 – Security
- 12 AAC 52.230 – Pharmacy technicians
- 12 AAC 52.210 – Pharmacist duties
- 12 AAC 52.423 – Remote pharmacy license
- 12 AAC 52.992 – Independent administration of vaccines and related emergency medications
- 12 AAC 52.990 – Display of license certificate
- 12 AAC 52.443 – Approval for shared pharmacy services by pharmacist
- 12 AAC 52.445 – Shared pharmacy services
- 12 AAC 52.446 – Shared pharmacy services during emergency

The Board of Pharmacy also intends to update its Facility Standards for Pharmacists appended to its statutes and regulations booklet. This was last revised in November 2016.

Goals and Objectives

Part I

FY 2021's goals and objectives, and how they were met:

The Board of Pharmacy identified fourteen (14) goals for FY2021, most of which have been met or are ongoing efforts to be incorporated into the board' strategic plan. Included in this section are the board's strengths, weaknesses, opportunities, and threats (SWOT), to illustrate its assets, capabilities, and internal and external challenges for both the aspects of licensing and the Prescription Drug Monitoring Program (PDMP).

SWOT 1. Pharmacy Licensing

Strengths	Weaknesses	Opportunities	Threats
•Complete board membership •Technologically adaptive •Responsive staff •Use of diverse communication channels •Established licensing policies and procedures •Special topic subcommittee meetings •Emergency preparedness regulations •Task list accountability and follow-up •Rapport with stakeholders (AKPhA, DHSS)	•Staff turnover	•Expedited online licensing through myAlaska •Expanded public comment opportunities	•Closure of services applicants need to complete licensure (exam services, inspectors, fingerprints) during COVID-19 •Shifting priorities due to COVID-19

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

SWOT 2. Prescription Drug Monitoring Program (PDMP)

Strengths	Weaknesses	Opportunities	Threats
•BOP established process to use as model by other boards: screening of requirements incorporated into applications; tracking of mandatory use compliance through designations; concurrent processing of PDMP registration and license renewals •Training documents and videos •Comprehensive website content and FAQs •Quarterly statistics reports provided to boards •Database enhancement features to display risk-based patient alerts	•Lack of receipt authority •Technological limitations •Personnel shortage •Differing priorities and processes amongst licensing boards	•PDMP Board Chairs meetings •Education and outreach •Awareness and feedback questionnaire •Collaboration with stakeholders (IHS, VA, military, HIE, DHSS, professional associations) •Grant applications •Development of disciplinary matrices	•Inconsistent funding opportunities •Low compliance due to time constraints and technological integration gaps •Perceived relevance of PDMP to opioid crisis •Perceived lack of enforcement for non-compliance

Goal #1: The board will continue to promote, preserve, and protect the public, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Status: met by

1.) Regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug rooms, wholesale drug distributors, outsourcing facilities, and third-party logistics providers
2.) Review and approval of collaborative practice agreements
3.) Administration of the Prescription Drug Monitoring Program (PDMP)
4.) Promulgation of regulations related to emergency preparedness
5.) Issuing guidance to pharmacy personnel in response to the COVID-19 pandemic

Goal #2: The board will continue to provide input and comment on any proposed regulations involving medications, pharmaceutical care, or the practice of pharmacy.

Status: The board was not aware of new opportunities to provide comment on proposed regulations.

Goals and Objectives (continued)

Goal #3: The board will continue to promote effective patient counseling by licensees.

Status: The board continues to promulgate regulations for mandatory patient counseling under 12 AAC 52.585. Additionally, the board amended 12 AAC 52.992(d) allowing a pharmacist intern to offer vaccine information statements (VIS) to patients. The board replaced *provide*, with *offer*, which improves patient engagement and encourages dialogue around these preventative services.

Goal #4: The board will continue to assess and evaluate the multi-state pharmacy jurisprudence examination (MPJE) and send two members to the MPJE Item Development workshop.

Status: This was not met due to threats; see SWOT 1.

Goal #5: The board will continue to assess and evaluate the licensing of pharmacy technicians and discuss the introduction, recognition, and duties for a nationally certified pharmacy technician.

Status: on March 27, 2020 the board adopted emergency regulations, including recognition of pharmacy technicians with national certifications. The emergency regulations took effect on April 3, 2020 and were adopted as permanent on May 28, 2020, the Board of Pharmacy adopted the emergency regulation changes to be made permanent. The permanent emergency regulation changes were approved, signed, and filed by the Lieutenant Governor on July 31, 2020.

Goal #6: The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

Status: the jurisprudence exam is still required for initial intern licensure. In the board's emergency preparedness regulations, repealed on April 3, 2020 and made permanent on July 31, 2020, the board removed the jurisprudence exam requirement for renewal of pharmacist and pharmacy technician licensure.

Goal # 7: The board will continue its affiliation with the National Association of Boards of Pharmacy (NABP) and send one member to the District 7 NABP meeting and two members to the annual NABP meeting.

Status: Dr. Ruffridge attended the District 7 NABP meeting held virtually on October 13, 2020. Following participation at this meeting, Dr. Ruffridge shared the district's resolutions with the Board of Pharmacy, which discussed the matter of a "just culture" regulatory approach during their December 3-4, 2020. Laura Carrillo and Justin Ruffridge attended the annual NABP meeting held virtually on May 13-14, 2021.

Goal #8: The board will continue to evaluate the impact of current regulations and the need for new regulations or amendments to current regulations to advance our mission.

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

Status: In drafting emergency preparedness regulations, and with the intent to make these changes permanent, the board also took this as an opportunity to assess changes to regulatory areas for improving patient care and expanding pharmacy services without jeopardizing the board's responsibility of effective oversight. These changes were made:

- Increasing service capacity by expanding the tasks for which a pharmacy technician with a national certification may perform, including performing final checks on non-controlled substances and clarify or obtain missing information on a prescription order
- Maximizing available pharmacy personnel resources by allowing a cashier or bookkeeper to work in a pharmacy without being licensed as a technician
- Expanding pharmacy intern capabilities, including transferring and performing final checks on prescription drug orders, marking the quantity and date of refills, dispensing electronically transmitted prescriptions, and dispensing substitutions if authorized by the practitioner
- Decreasing unnecessary administrative requirements, including reducing documentation review for items replaced by applicant and licensee attestations
- Improving continuation of patient care by removing the 30-day supply limitation and allowing a pharmacist or pharmacist intern to dispense any quantity of a prescription order for non-controlled substances
- Expanding shared pharmacy services to include pharmacist interns, pharmacy technicians with national certification, and allowing for counseling and monitoring of drug therapy through these services

Goal #9: The board will continue to assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and support continuing funding and enhancement for the PDMP.

Status: The board continues to administer the PDMP for all six affected healthcare boards and manages deliverables from three separate federal grants. The board initiated a PDMP Board Chairs committee in October 2020, which meets bi-weekly to discuss challenges and solutions to registration and use. Through its PDMP manager, the board provides quarterly statistics reports to prescribing boards on metrics concerning dangerous combinations of therapy, high MME prescribing, and registration and review compliance. The Board of Pharmacy established its own disciplinary guidelines for failure to register and failure to report, which are monitored an on-going and quarterly basis, respectively. See SWOT 2.

Goal #10: The board will monitor, assess, evaluate, and modify the Alaska PDMP based on the best interest of the
public and profession.

Status: the board launched an Awareness and Feedback questionnaire from June 10, 2021 to June 30, 2021to gauge user interaction and compliance, and to assess regulatory and technological gaps to access, visibility, and use. In an effort to standardize registration timeframes and increase timely access to the system, the board proposed a 30-day registration timeframe, which became effective May 6 of FY2021.

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

Goal #11: The board will develop a strategic plan around communication, administration, regulation and legislation, licensure, and enforcement.

Status: The board reviewed and approved its 2021 strategic plan in May 2021 and will review and approve their 2022 strategic plan in September 2021.

Goal #12: The board will continue its affiliation and collaboration with the Alaska Pharmacists Association, including attendance at its annual meetings.

Status: On February 14, 2021, Dr. Ruffridge presented to the AKPhA a summary of the board's regulatory changes in 2020. PDMP Manager, Lisa Sherrell, also provided an overview presentation of the database and aggregate statistics.

Goal #13: The board will support its staff in participating at training opportunities and attendance at professional
conferences, including training to support assigned investigators.

Status: Staff participated in training opportunities and conferences virtually as permissible, including the NABP District 7 Meeting (October 13, 2020), CLEAR Investigator Training (October 19 – November 2, 2020), Pain Clinic Closure Workshop (January 12 and 14, 2021), National Drug Abuse and Heroin Summit (April 5-8, 2021), and Annual NABP Meeting (May 13-14, 2021).

Goal #14: The board will continue to simply its statutes and regulations by assessing outdated, burdensome, or unnecessary regulations.

Status: the board's right-touch regulations subcommittee met on November 18, 2020 to discuss potential redundant and/or obsolete regulations. As a result of this subcommittee meeting, the board requested guidance from the DOL around the definition of "practice of pharmacy" and limitations around the independent administration of drugs. The DOL introduced the concept of Negative Implication Canon, which is used in legal drafting and states that the explicit mention of certain topics excludes other topics not clearly mentioned. This term was brought forward to support the HB 145 and to articulate that because statute calls out independent administration of vaccines and emergency medications, it prohibits pharmacists from the independent administrative of other therapies. The board will continue to pursue right-touch regulations in FY2021, including but not limited to the following areas:

- Simplifying pharmacy licensure, including replacing the inspection report requirement with an attestation
- Simplifying pharmacist licensure, including repealing the transcripts requirement
- Simplifying pharmacist intern licensure, including repealing the jurisprudence questionnaire
- Clarifying procedures for facilities when a change of address, ownership, name, or manager has occurred

Goals and Objectives

Part II

FY 2022's goals and objectives, and proposed methods to achieve them. Describe any strengths, weaknesses, opportunities, threats and required resources:

Below is the Board of Pharmacy's 2021 strategic plan, which includes its priority goals and strategies. The board intends to continue pursuing these goals in FY2022.

ALASKA BOARD OF PHARMACY
2021 STRATEGIC PLAN

The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

GUIDING PRINCIPLES	GOALS	STRATEGIES
COMMUNICATION	**1.** Engage in effective communication and promote transparency of public information.	**1.1** Improve customer service by providing timely updates to applicants and licensees. **1.2** Encourage appropriate disclosure of information related to licensing and investigative processes. **1.3** Maximize communication channels through the Board of Pharmacy website and List Service. **1.4** Increase collaboration with health care licensing boards and key stakeholders to address important health issues.
ADMINISTRATION	**2.** Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	**2.1** Avoid delays in application processing by maintaining adequate staffing and exploring retention strategies. **2.2** Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process. **2.3** Automate licensure through online applications. **2.4** Exercise fiscal discipline through effective budget management.
LICENSURE	**3.** Ensure competency and qualifications prior to licensure and renewal.	**3.1** Adhere to established licensing standards by reviewing education, experience, and examination requirements. **3.2** Periodically review applications and forms for alignment with existing requirements.
REGULATION & ENFORCEMENT	**4.** Grow the economy while promoting community health and safety.	**4.1** Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety. **4.2** Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP). **4.3** Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance. **4.4** Establish disciplinary guidelines and conduct random audits to ensure safety protocols and competencies are met. **4.5** Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arises.

For more information, please visit the following resources:

Board of Pharmacy Homepage: pharmacy.alaska.gov
Prescription Drug Monitoring Program (PDMP): pdmp.alaska.gov

Email: pharmacy@alaska.gov
Phone: 907-465-1073

Goals and Objectives (continued)

Part II (continued)

FY 2022's goals and objectives, and proposed methods to achieve them. Describe any strengths, weaknesses, opportunities, threats and required resources:

Goal #1: engage in effective communication and promote transparency of public information.

Strategy 1.1: Improve customer service by providing timely updates to applicants and licensees.

Strategy 1.2: Encourage appropriate disclosure of information related to licensing and investigative processes.

Strategy 1.3: Maximize communication channels through the Board of Pharmacy website and List Service.

Strategy 1.4: Increase collaboration with health care licensing boards and key stakeholders to address important health issues.

Goal #2: adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.

Strategy 2.1: Avoid delays in application processing by maintaining adequate staffing and exploring retention strategies.

Strategy 2.2: Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process.

Strategy 2.3: Automate licensure through online applications.

Strategy 2.4: Exercise fiscal discipline through effective budget management.

Goal #3: Ensure competency and qualifications prior to licensure and renewal.

Strategy 3.1: Adhere to established licensing standards by reviewing education, experience, and examination requirements.

Strategy 3.2: Periodically review applications and forms for alignment with existing requirements.

Goal #4: Grow the economy while promoting community health and safety.

Strategy 4.1: Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety.

Strategy 4.2: 4.2Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP).

Strategy 4.3: Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance.

Strategy 4.4: Establish disciplinary guidelines and conduct random audits to ensure safety protocols and competencies are met.

Strategy 4.5: 4.5Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arises.

Board of Pharmacy
Fiscal Year 2021 Annual Report

Sunset Audit Recommendations

Date of Last Legislative Audit: **August 7, 2017**
Board Sunset Date: **June 30, 2022**

Audit Recommendation:	DCBPL's chief investigator should work with the director to improve the timeliness of investigations.
Action Taken:	A Standard Operating Procedure (SOP) was adopted to require investigative staff to enter case notes explaining any gaps between activities greater than sixty days. In addition, each member of staff is held accountable for timeliness of investigative actions.
Next Steps:	Monitor for effectiveness.
Date Completed:	January 5, 2018

Audit Recommendation:	DCBPL's director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.
Action Taken:	The division will continue to provide training to staff to ensure they are aware of their roles and responsbilities in preserving an accurate and complete adminstrative record.
Next Steps:	
Date Completed:	

CORRESPONDENCE

Expanding Access to COVID 19 Therapeutics

HHS PREP Act Declaration: 9 th Amendment

Commitment to Ending the COVID-19 Pandemic

Throughout the COVID-19 response, the federal government has remained steadfast in providing support to states and territories as part of the whole of America approach to fighting the pandemic. The Biden administration remains committed to developing safe and effective therapeutics against the COVID 19 virus and making these drugs accessible across the country.

To support this priority effort, the Department of Health and Human Services (HHS) amended the Public Readiness and Emergency Preparedness (PREP) Act declaration to provide liability protection to **licensed pharmacists, pharmacy technicians, and pharmacy interns**.

By expanding PREP Act coverage to include these trained professionals for the administration of covered COVID 19 therapeutics, we are providing a pathway for increased access to COVID 19 therapeutics, particularly in surge states with rising numbers of COVID 19 cases and in rural areas where access to inpatient and outpatient services may be more limited.

COVID-19 PREP Act Declaration

What is a PREP Act Declaration?

The PREP Act allows the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that extends liability protections to entities and individuals who manufacture, distribute, or administer covered medical countermeasures against a public health threat or emergency. In March 2020, the Secretary issued a PREP Act Declaration covering COVID 19 tests, drugs, and vaccines providing liability protections to manufacturers, distributors, SLTTs, licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID 19 countermeasures.

What is the Impact on SLTTs?

The PREP Act and Declaration preempt state requirements, such as more limited licensing or scope of practice requirements, that effectively prohibit a qualified person from prescribing, dispensing, or administering COVID 19 therapeutics. Requirements that do not effectively prohibit qualified persons, such as additional training, are not preempted. Ultimately, states and territories may choose which qualified persons to use for administering COVID 19 therapeutics in their jurisdiction.

PREP Act Declaration 9th Amendment Who's Covered?

Qualified Persons

The 9th amendment to the COVID 19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for **pharmacy technicians and pharmacy interns** to administer COVID 19 therapeutics to populations authorized by the FDA when the following criteria are met:

The COVID-19 therapeutic must be authorized, approved, licensed, or cleared by the FDA.
In the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be:
ordered for subcutaneous, intramuscular, or oral administration and
in accordance with the FDA approval, authorization, clearance, or licensing.
In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be: administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, clearance, or licensing.
In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician.

Legal Authorities

PREP Act
Public Readiness and Emergency Preparedness (PREP) Act Overview
PREP Act Glossary of Terms
PREP Act Question and Answers

Other Legal Authorities
Legal Authorities Overview
Legal Authority of the Secretary
Public Health Emergency (PHE) Declaration
PHE Frequently Asked Questions
1135 Waivers
Emergency Use Authorization
Pandemic and All-Hazards Preparedness Act of 2006
Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include:

- hands-on injection technique,
- clinical evaluation of indications and contraindications of COVID-19 therapeutics,
- the recognition and treatment of emergency reactions to COVID-19 therapeutics, and
- any additional training required in the FDA approval, authorization, clearance, or licensing.

The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.

The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events.

The licensed pharmacist, the licensed or registered pharmacy intern, and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.

This page last reviewed: September 09, 2021

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

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BOARD OF PHARMACY – QUESTIONS AND ANSWERS
Dispensing Ivermectin for COVID-19 September 2, 2021

This update is intended to support pharmacists and prescribers in navigating treatment options during the ongoing pandemic. The Board of Pharmacy recognizes the recent increase of patients receiving prescriptions for the anti-parasitic drug, Ivermectin, to treat COVID-19. The board also recognizes the challenging position our frontline pharmacists are facing in advising patients regarding this treatment, recommending alternatives, and consulting with prescribers. The board continues to support pharmacists in exercising their independent professional judgment and approaching each patient/prescriber scenario individually.

FAQs:

Q1. If a patient receives a prescription for ivermectin, am I obligated to fill it?
A1. If, after assessing for the patient's severity of illness, underlying condition(s), drug interaction(s), and other considerations to determine the appropriateness of treatment, the pharmacist may choose to fill this prescription, but is not obligated to. Pharmacists are encouraged to seriously consider the AMA, APhA, and ASHP's position to *"strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial."*

Q2. Can I contact the practitioner to discuss a patient's ivermectin prescription?
A2. Yes. Pharmacists are encouraged to contact or attempt to contact the practitioner to discuss appropriateness of treating the patient with ivermectin.

Q3. What is an appropriate response to patients expecting their prescription to be dispensed?
A3. The following are all appropriate examples:

- Inform the patient ivermectin is not FDA approved, it is not supported by the AMA, APhA, and ASHP, and that there is insufficient data to support its use as a safe and effective treatment for COVID-19.
- Recommend an alternative treatment option, such as monoclonal antibodies.
- Recommend the patient discuss this with their primary care provider.
- Recommend the patient seek care immediately by visiting the emergency room if moderate to severe symptoms are present.
- Other recommendations the pharmacist believes is in the best interest of the patient.

Q4. I have attempted to refuse to fill ivermectin prescriptions, but the patient continues to insist this must be filled. If, after consulting with the prescribing practitioner, s/he also reiterates the need for it to be filled, what is the most appropriate course of action?
A4. Pharmacists can only do their best to explain the reason behind refusing to fill. If consulting with the practitioner provides the pharmacist with additional information to determine the prescription should be dispensed, that decision should be made because the pharmacist believes it is in the best interest of the patient to do so, not because of pressure from the practitioner to fill it. If either a practitioner or a pharmacist is concerned about the prescribing or dispensing of this medication, the licensee may choose to file a complaint with the Investigative Unit.

Resources

- AMA, APhA, ASHP opposition (September 1, 2021): https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19
- FDA guidance on Ivermectin (March 5, 2021): https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19
- CDC Health Advisory (August 26, 2021): https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf
- CBPL COVID page: https://www.commerce.alaska.gov/web/cbpl/CBPLCOVID-19Information.aspx

PRESS RELEASES

AMA, APhA, ASHP statement on ending use of ivermectin to treat COVID-19

SEP 1, 2021

WASHINGTON, DC – The American Medical Association (AMA), American Pharmacists Association (APhA), and American Society of Health-System Pharmacists (ASHP) **strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial.**

Ivermectin is approved by the U.S. Food and Drug Administration (FDA) for human use to treat infections caused by internal and external parasites. It is not approved to prevent or treat COVID-19. Ivermectin is also available to treat certain veterinary conditions; medications formulated or intended for use in animals should not be used by humans. We are alarmed by reports that outpatient prescribing for and dispensing of ivermectin have increased 24-fold since before the pandemic and increased exponentially over the past few months. As such, we are calling for an immediate end to the prescribing, dispensing, and use of ivermectin for the prevention and treatment of COVID-19 outside of a clinical trial. In addition, we are urging physicians, pharmacists, and other prescribers—trusted health care professionals in their communities—to warn patients against the use of ivermectin outside of FDA-approved indications and guidance, whether intended for use in humans or animals, as well as purchasing ivermectin from online stores. Veterinary forms of this medication are highly concentrated for large animals and pose a significant toxicity risk for humans.

The U.S. Centers for Disease Control and Prevention (CDC) and the FDA have issued advisories indicating that ivermectin is not authorized or approved for the prevention or treatment of COVID-19. The National Institutes of Health, World Health Organization, and Merck (the manufacturer of the drug) all state there is insufficient evidence to support the use of ivermectin to treat COVID-19. The Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 also recommend against the use of ivermectin outside of a clinical trial.

Use of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients. Calls to poison control centers due to ivermectin ingestion have increased five-fold from their pre-pandemic baseline. A recent CDC Health Alert Network Advisory (PDF) recommends that health care professionals should counsel patients against use of ivermectin as a treatment for COVID-19, including emphasizing the potentially toxic effects of this drug, including "nausea, vomiting, and diarrhea. Overdoses are associated with hypotension and neurologic effects such as decreased consciousness, confusion, hallucinations, seizures, coma, and death."

For more information, we encourage patients and health care providers to consult the FDA's Consumer Update on Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 and the CDC Health Alert Network Advisory on the Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Products Containing Ivermectin to Prevent or Treat COVID-19.

Patients are encouraged to talk to their physicians, pharmacists, and other prescribers about currently available therapies authorized or approved for the treatment or prevention of COVID-19. The most effective ways to limit the spread of COVID-19 are to get vaccinated, wear a face mask, stay at least six feet from others in public places, wash hands frequently, and avoid large crowds of people. Our organizations strongly urge eligible unvaccinated individuals to get vaccinated.

AMA COVID-19 Resource Center for Physicians

APhA COVID-19 Resource Center

ASHP COVID-19 Resource Center

Media Contact:

AMA Media & Editorial

ph: (312) 464-4430
media@ama-assn.org

About the American Medical Association

The American Medical Association is the physicians' powerful ally in patient care. As the only medical association that convenes 190+ state and specialty medical societies and other critical stakeholders, the AMA represents physicians with a unified voice to all key players in health care. The AMA leverages its strength by removing the obstacles that interfere with patient care, leading the charge to prevent chronic disease and confront public health crises and, driving the future of medicine to tackle the biggest challenges in health care.

More about:

AMA Press Center

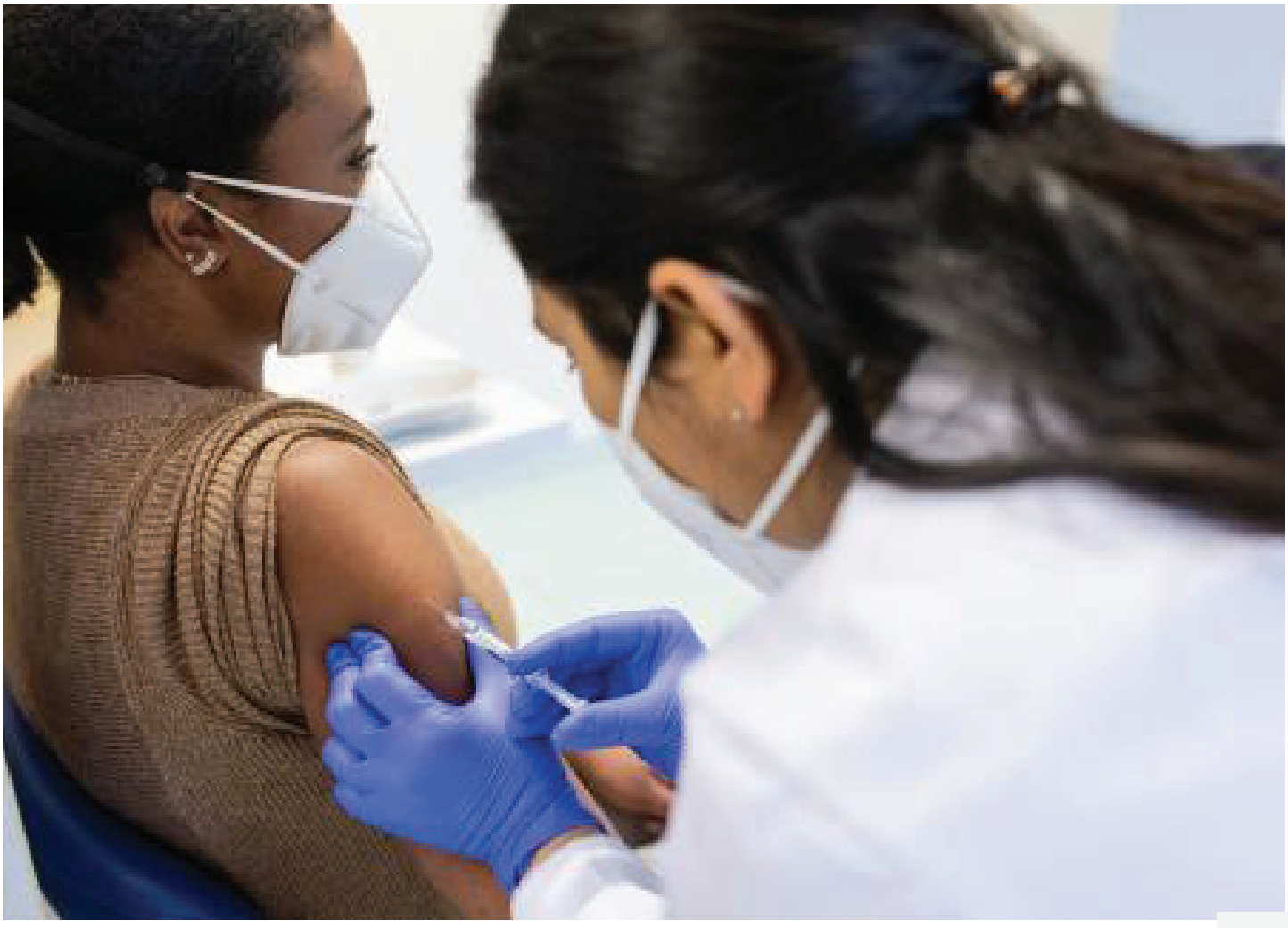
COVID-19 Medication & Treatment Guidance

Coronavirus (COVID-19)

Coronavirus Masking in Public

Coronavirus Vaccines

FEATURED STORIES



VACCINATIONS

What to tell immunocompromised patients about COVID-19 vaccines

SUSTAINABILITY

Redefining "cause of death" meaning would upend medical liability law

MEDICAL SCHOOL

Q&A: How 2 med students stepped up during a mid-air emergency

The AMA promotes the art and science of medicine and the betterment of public health.

Board of Pharmacy - Prescription Drug Monitoring Program
Approved Disciplinary Matrix ~~as of February 18, 2021~~

Complaint	Proposed Sanctions
Registration (AS 17.30.200(e)(n), 12 AAC 52.855): • No registration • Delayed registration – not registered within 30 days • Delayed dispensing status, including dispensation exemption form – not submitted within 10 days	(Notice sent on July 7, 2020 via board letter to all pharmacists with Alaska addresses). $250 civil fine beginning on October 1, 2020 (or after 30 days of initial licensure or after beginning to dispense schedule II, III, or IV federally controlled substances) and an additional $25 per day until registration is completed. $250.00 civil fine for each day after the 10th day of not submitting the dispensing notice of change to the board.
Delinquent Reporting (AS 17.30.200(b)(e), 12 AAC 52.865): • Daily reporting (12 AAC 52.865)(b)) • Delayed dispensing/distributing status – not submitted within 10 days	(Warning issued September 16, 2020 via board letter to all licensees). As of January 1, 2021, quarterly compliance audits will track* delinquent submissions of data to the PDMP. • First reprimand: $5,000 civil fine for continued submission delinquencies • ~~Continued submission delinquencies may result in license suspension. A "continued submission delinquency" means a pharmacy that has not reported or responded to notices by the Board.~~ Reporting delinquency is defined as a pharmacy that missed at least one reporting day within a 30-day period. ○ Appear on monthly list for first time = warning letter ○ Appear on monthly list again = $5,000 civil fine • Dispensing status not submitted timely: $250 civil fine for each day after the 10th date of not submitting the notice of change to the board
Unauthorized Access (AS 17.30.200(d)(4))	TBD

*During its May 2021 meeting, the board agreed to begin monitoring compliance daily with referrals to the Investigative Unit to include all pharmacies delinquent on at least one day. The new monthly analysis will begin on July 1st and the first round of referrals will be transmitted on August 1st.

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BUDGET

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 14	FY 15	Biennium	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21 1st - 3rd QTR
Revenue											
Revenue from License Fees	$ 673,100	$ 269,646	$ 942,746	$ 802,230	$ 208,755	$ 1,010,985	$ 801,317	$ 213,770	$ 1,015,087	$ 631,105	$ 996,647
Allowable Third Party Reimbursements	1,701	-	1,701	-	3,256	3,256	210	962	1,172	$ -	$ -
TOTAL REVENUE	$ 674,801	$ 269,646	$ 944,447	$ 802,230	$ 212,011	$ 1,014,241	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 996,647
Expenditures											
Non Investigation Expenditures											
1000 - Personal Services	132,988	115,222	248,210	156,115	151,947	308,062	204,727	194,745	399,472	199,334	203,289
2000 - Travel	24,054	24,548	48,602	16,676	11,119	27,795	13,704	8,299	22,003	2,641	-
3000 - Services	17,003	4,569	21,572	13,361	14,293	27,654	21,960	27,781	49,741	45,283	28,581
4000 - Commodities	69	90	159	111	519	630	-	26	26	521	-
5000 - Capital Outlay	-	-	-	-	-	-	-	-	-	-	-
Total Non-Investigation Expenditures	174,114	144,429	318,543	186,263	177,878	364,141	240,391	230,851	471,242	247,779	231,870
Investigation Expenditures											
1000-Personal Services	49,292	49,044	98,336	68,935	63,727	132,662	68,679	69,997	138,676	57,738	71,899
2000 - Travel								-	-	1,260	-
3023 - Expert Witness	-	-	-	-	2,800	2,800	-	-	-	-	-
3088 - Inter-Agency Legal	7,630	4,580	12,210	1,451	23,355	24,806	-	3,062	3,062	2,537	85
3094 - Inter-Agency Hearing/Mediation	-	-	-	-	883	883	-	-	-	694	152
3000 - Services other								400	400	269	13
4000 - Commodities								-	-	-	-
Total Investigation Expenditures	56,922	53,624	110,546	70,386	90,765	161,151	68,679	73,459	142,138	62,498	72,149
Total Direct Expenditures	231,036	198,053	429,089	256,649	268,643	525,292	309,070	304,310	613,380	310,277	304,019
Indirect Expenditures											
Internal Administrative Costs	123,716	72,555	196,271	128,025	123,008	251,033	150,986	155,128	306,114	164,443	123,332
Departmental Costs	45,898	48,021	93,919	48,707	73,682	122,389	78,139	81,374	159,513	58,131	43,598
Statewide Costs	28,298	25,287	53,585	15,564	26,226	41,790	30,555	27,069	57,624	33,868	25,401
Total Indirect Expenditures	197,912	145,863	343,775	192,296	222,916	415,212	259,680	263,571	523,251	256,442	192,331
									-		
TOTAL EXPENDITURES	**$ 428,948**	**$ 343,916**	**$ 772,864**	**$ 448,945**	**$ 491,559**	**$ 940,504**	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 496,350**
Cumulative Surplus (Deficit)											
Beginning Cumulative Surplus (Deficit)	$ 29,896	$ 275,749		$ 201,479	$ 554,764		$ 275,216	$ 507,993		$ 154,844	$ 219,230
Annual Increase/(Decrease)	245,853	(74,270)		353,285	(279,548)		232,777	(353,149)		64,386	500,297
Ending Cumulative Surplus (Deficit)	$ 275,749	$ 201,479		$ 554,764	$ 275,216		$ 507,993	154,844		219,230	719,527
Statistical Information											
Number of Licenses for Indirect calculation	4,134	4,756		4,649	5,068		5,680	6,203		5,934	

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: Fee reduction FY20*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.*

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Appropriation Name (Ex)	(All)
Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures	**Object Type Name (Ex)**		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	145,282.36		145,282.36
1014 - Overtime	633.60		633.60
1023 - Leave Taken	24,365.14		24,365.14
1028 - Alaska Supplemental Benefit	10,409.78		10,409.78
1029 - Public Employee's Retirement System Defined Benefits	1,916.03		1,916.03
1030 - Public Employee's Retirement System Defined Contribution	8,539.69		8,539.69
1034 - Public Employee's Retirement System Defined Cont Health Reim	5,485.59		5,485.59
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	2,045.59		2,045.59
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	19,322.46		19,322.46
1039 - Unemployment Insurance	259.46		259.46
1040 - Group Health Insurance	46,325.64		46,325.64
1041 - Basic Life and Travel	68.44		68.44
1042 - Worker's Compensation Insurance	1,579.54		1,579.54
1047 - Leave Cash In Employer Charge	3,440.90		3,440.90
1048 - Terminal Leave Employer Charge	2,366.19		2,366.19
1053 - Medicare Tax	2,359.58		2,359.58
1063 - GGU Business Leave Bank Usage	-		-
1069 - SU Business Leave Bank Contributions	29.31		29.31
1077 - ASEA Legal Trust	191.02		191.02
1079 - ASEA Injury Leave Usage	19.46		19.46
1080 - SU Legal Trst	17.39		17.39
1970 - Personal Services Transfer	530.71		530.71
3000 - Training/Conferences		2,397.00	2,397.00
3035 - Long Distance		7.12	7.12
3045 - Postage		30.35	30.35
3046 - Advertising		1,144.53	1,144.53
3088 - Inter-Agency Legal		17,541.90	17,541.90
3094 - Inter-Agency Hearing/Mediation		151.90	151.90
3100 - Inter-Agency Safety		2,205.00	2,205.00
3085 - Inter-Agency Mail		5,352.99	5,352.99
Grand Total	**275,187.88**	**28,830.79**	**304,018.67**

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Prescription Drug Monitoring Program	FY 14	FY 15	Biennium	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21 1st - 3rd QTR
Revenue											
Revenue from License Fees	$ -	$ -	$ -			$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 166,915
Allowable Third Party Reimbursements	-	-	-	-	-	-	-	-	-	$ -	$ -
TOTAL REVENUE	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 166,915
Expenditures											
Non Investigation Expenditures											
1000 - Personal Services			-			-	-	6,043	6,043	41,343	1,552
2000 - Travel			-			-	-	-	-	796	-
3000 - Services			-			-	-	11	11	6,155	1,162
4000 - Commodities			-			-	-	-	-	-	-
5000 - Capital Outlay	-	-	-	-		-	-	-	-	-	-
Total Non-Investigation Expenditures	-	-	-	-	-	-	-	6,054	6,054	48,294	2,714
Investigation Expenditures											
1000-Personal Services			-			-		-	-	-	-
2000 - Travel								-	-	-	-
3023 - Expert Witness			-			-	-	-	-	-	-
3088 - Inter-Agency Legal			-			-	-	-	-	-	-
3094 - Inter-Agency Hearing/Mediation			-			-	-	-	-	-	-
3000 - Services other								-	-	-	-
4000 - Commodities								-	-	-	-
Total Investigation Expenditures	-	-	-	-	-	-	-	-	-	-	-
Total Direct Expenditures	-	-	-	-	-	-	-	6,054	6,054	48,294	2,714
Indirect Expenditures											
Internal Administrative Costs			-			-		-	-	-	-
Departmental Costs			-			-		-	-	-	-
Statewide Costs			-			-		-	-	-	-
Total Indirect Expenditures	-	-	-	-	-	-	-	-	-	-	-
TOTAL EXPENDITURES	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 6,054	$ 6,054	$ 48,294	$ 2,714
Cumulative Surplus (Deficit)											
Beginning Cumulative Surplus (Deficit)		$ -		$ -	$ -		$ -	$ -		$ 84,711	$ 62,567
Annual Increase/(Decrease)	-	-		-	-		-	84,711		(22,144)	164,201
Ending Cumulative Surplus (Deficit)	$ -	$ -		$ -	$ -		$ -	84,711		62,567	226,768
Statistical Information											
Number of Licenses for Indirect calculation								-	-	-	

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: No fee change*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.*

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	PDMP

Sum of Budgetary Expenditures	Object Type Name (Ex)		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	41,610.20		41,610.20
1014 - Overtime	705.66		705.66
1023 - Leave Taken	2,841.30		2,841.30
1028 - Alaska Supplemental Benefit	2,787.21		2,787.21
1029 - Public Employee's Retirement System Defined Benefits	221.77		221.77
1030 - Public Employee's Retirement System Defined Contribution	2,356.56		2,356.56
1034 - Public Employee's Retirement System Defined Cont Health Reim	1,624.09		1,624.09
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	564.59		564.59
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	5,221.94		5,221.94
1039 - Unemployment Insurance	84.66		84.66
1040 - Group Health Insurance	12,103.27		12,103.27
1041 - Basic Life and Travel	17.82		17.82
1042 - Worker's Compensation Insurance	423.20		423.20
1047 - Leave Cash In Employer Charge	927.00		927.00
1048 - Terminal Leave Employer Charge	625.78		625.78
1053 - Medicare Tax	636.86		636.86
1069 - SU Business Leave Bank Contributions	6.25		6.25
1077 - ASEA Legal Trust	59.77		59.77
1079 - ASEA Injury Leave Usage	1.90		1.90
1080 - SU Legal Trst	7.29		7.29
1970 - Personal Services Transfer	(71,055.78)		(71,055.78)
3002 - Memberships		300.00	300.00
3033 - Software Maintenance		18,668.76	18,668.76
3088 - Inter-Agency Legal		84.58	84.58
1979 - Personal Services Management Allocations	(219.79)		(219.79)
3970 - Contractual Transfer		(18,668.76)	(18,668.76)
3085 - Inter-Agency Mail		777.18	777.18
Grand Total	**1,551.55**	**1,161.76**	**2,713.31**

INDUSTRY UPDATES

From: AKPhA
To: AKPhA
Subject: AKPhA Update
Date: Friday, September 10, 2021 1:25:54 PM
Attachments: image001.png
image002.png

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Survey for Booster Planning—Please Respond By September 14th

The State of Alaska is preparing for COVID-19 boosters and is seeking to collect data with a quick survey on the capacity and plans of our enrolled COVID-19 vaccine providers. One survey is for **pharmacies** and the other survey is for **providers/clinics.** Please only complete one survey per facility**.** Thank you for your continued work to support Alaskans getting vaccinated against COVID-19.

CV Review Program—Due September 13th

The AKPhA Academy of Health-System Pharmacy is continuing its curriculum vitae (CV) review program. CV submitters will be paired with a volunteer reviewer to assist in the development of an effective CV. Students have until **September 13, 2021** to submit their draft CV and we will match students with volunteer mentors shortly after that deadline. Mentors/Students attending the Fall CE Conference in-person will be paired accordingly, but we hope all mentors can follow up with students by mid-October before the Pharmacy Fair. Follow this link to volunteer as a mentor or to submit your CV: https://alaskapharmacy.org/resources/cv-review-program/

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AKPhA Now Accepting Scholarship Applications & Nominations

AKPhA annually offers three scholarships to students to promote education and interest in pharmacy careers:
The Pharmacy Student Scholarship—$1,500
The Pre-Pharmacy Scholarship—$1,000
The Pharmacy Technician Scholarship—$500
For a description of the scholarships, to nominate a student, or to apply online, go to: https://alaskapharmacy.org/resources/scholarships/
Deadline for Receipt of Student Applications: November 30th
Our scholarship program is made possible by donations and proceeds from the Silent Auction held during the Annual Convention. Click HERE to make a monetary donation now!

AKPhA Print Newsletter

The Third Quarter "Alaska Pharmacy Newsletter" was mailed to members end of last week. Members can also access this edition online by logging in to our website at: https://alaskapharmacy.org/resources/newsletters/ Hard copies of the newsletter are printed and mailed every other quarter.

AKPhA ACADEMY OF HEALTH-SYSTEM PHARMACY FALL CE CONFERENCE—Register Today!
Saturday, September 25, 2021
Alyeska Hotel
IN-PERSON & ONLINE OPTIONS AVAILABLE
Please note masks are required for in-person attendance.
Conference Chair Megan Penner
Sponsored By: Abbvie

Registration

Register online now at: https://alaskapharmacy.org/event/5th-annual-akpha-academy-of-health-system-pharmacy-fall-ce-conference-2/
Must be a member of AKPhA and the Academy (dues can be paid online) to attend. Manual registration form also available online.

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Schedule—Updated 8/20/21

Schedule updates are posted frequently. This activity is eligible for approximately 7.25 hours of pharmacist and technician specific CE credit.

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Hotel Room Reservations

While the August 24th deadline to book rooms has passed, Alyeska Hotel may still honor our conference group rate of $142 sgl/dbl occupancy if space is available. Please reference **Alaska Pharmacists Association or "Block Code API25H"** and email reservations@alyeskaresort.com or call 907-754-2111, extension 1.

PHARMACY LEADERSHIP DEVELOPMENT—Register Today!
Friday, September 24, 2021
UAA Professional Studies Building, Room 107 ***(Note location change)***
Program Chair Courtney Graziano
Sponsored By: Bristol Myers Squibb

Schedule to Date

Pharmacists, residents, students and technicians are welcome to attend this FREE inaugural event! The goal of this half-day program is to create connections

with other pharmacy colleagues who have an interest in developing leadership skills. This event is not accredited for continuing education credit. You must be an AKPhA member and register in advance as limited spots are available: https://alaskapharmacy.org/event/inaugural-pharmacy-leadership-development/

Message from Executive Director

It has been an honor serving as the Executive Director of the Alaska Pharmacists Association for the past seven years. This is a strong organization with an engaged, caring group of members. I couldn't be more grateful for the opportunities and relationships I've gained working in this position, and will miss you all as I move on to the next chapter in my career. The Board of Directors and I have updated the ED position description and it is posted at: **https://alaskapharmacy.org/resources/careers/** Please consider applying or sharing the information with others you know who might be interested in this position and working with AKPhA. **Initial review of applications will be on September 13th**. My last day with the Association will be September 25th.

Thank you for your support and participation with AKPhA!

Molly Gray
Executive Director
Alaska Pharmacists Association
203 W 15th Ave #100
Anchorage, AK 99501
Phone (907) 563-8880, FAX (907) 563-7880
Office Hours: Monday - Friday, 10:30 am - 3:00 pm
www.alaskapharmacy.org

Dedicated to Preserving, Promoting &
Leading the Profession of Pharmacy in Alaska

REGISTRATION OPEN FOR THE FOLLOWING EVENTS:

AKPhA Academy of Health-System Pharmacy
Fall CE Conference, Alyeska Hotel
September 25, 2021

Pharmacy Leadership Development
Updated UAA Professional Studies Bldg, Room 107/TBD
September 24, 2021

ADMIN BUSINESS

THE STATE of ALASKA
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
Phone: (907) 465-2550
Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy*

DRAFT

Pharmacy/Facility Inspection Discrepancy Acknowledgement Form

This form is required to be submitted to the Board of Pharmacy within 10 days as required by 12 AAC 52_____ if discrepancies are identified during a random inspection of the pharmacy or facility.

License Type

License Type:	[ ] Pharmacy [ ] Drug Room [ ] Central/Remote Pharmacy [ ] Wholesaler

Licensee Information

Pharmacy/Facility Name:				
Alaska License #:		**Phone #:**		
Physical Address:	Street/PO Box:	City:	State:	Zip Code:
Pharmacist-in-Charge or Facility Manager Name:				
Email Address:				

Inspection Information

Date of Inspection:	(mm/dd/yyyy)	**Date Inspection Results Provided:**	(mm/dd/yyyy)
Summary of Discrepancies:			

Acknowledgment

By providing my signature below, I acknowledge discrepancies in safety standards or requirements were identified upon a random inspection of the above pharmacy or facility. I further acknowledge these discrepancies will be addressed and corrected.

Signature of PIC/Manager:		**Date:**	(mm/dd/yyyy)

THE STATE of ALASKA
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

Board of Pharmacy
PO Box 110806, Juneau, AK 99811-0806
Phone: (907) 465-2550
Website: Pharmacy.Alaska.Gov

Reinstatement of Pharmacist License Lapsed More Than 2 Years

A pharmacist whose license has lapsed or expired for more than two (2) years may not practice pharmacy until the license is reinstated by the board. To apply for reinstatement, submit this application along with supporting documents indicating continuous practice history, and all applicable fees required by 12 AAC 02.310. If your license has been in lapsed states for less than two years, submit the renewal application (#08-4096).

1. APPLICATION

Complete, signed, and notarized application (#08-4225, pages 1-4)

2. RENEWAL FEE(S)

- 2016 – 2018: $240.00
- 2018 – 2020: $240.00
- 2020 – 2022: $200.00

3. CONTINUOUS PRACTICE

Indicate whether you have been in continuous practice for at least 6 months in another jurisdiction for each year your Alaska license was not in active status (#08-4225b). The substitution for this requirement is to take the examinations described in section 6 of these instructions.

4. STATE LICENSURE AND PRACTICE HISTORY

Indicate the jurisdictions in which you have ever held a license and the dates of active practice in those jurisdictions (#08-4109a).

5. CONTINUING EDUCATION

Attest that you completed all the continuing education requirements that would have been required to maintain a current Alaska pharmacist license for each renewal period your license was lapsed or expired. You must also submit all copies of continuing education certificates meeting the requirements of 12 AAC 52.320 – 12 AAC 52.350.

- 2016 – 2018: 30 hours
- 2018 – 2020: 30 hours
- 2020 – 2022: 30 hours

6. ADDITIONAL REQUIRED DOCUMENTATION

Option A

- Retake and pass the Multistate Jurisprudence Examination (MPJE) and the North American Pharmacy Licensing Examination (NAPLEX). Arrangements to take the examination are made through the National Association of Boards of Pharmacy (NABP). Eligibility will be granted by the board after review of your application.

Option B

- Submit the verification of continuous practice (form included);
- Pass the Multistate Jurisprudence Examination (MPJE); and
- Arrange for license verifications from all states and jurisdictions in which you have ever held a license to be sent directly to the Alaska Board of Pharmacy. A blank verification form is provided for your convenience (make additional copies as needed). The board will also accept license verifications sent electronically via email if the verification comes directly from the licensing agency.

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Reinstatement of Pharmacist License Lapsed More Than 2 Years

PART I Payment of Fees

Check all that apply

Required Fees:	☐ 2016 - 2018	**$240.00**
	☐ 2018 - 2020	**$240.00**
	☐ 2020 - 2022	**$200.00**

PART II Applicant Information

Full Legal Name:			
Provide all other names used (maiden, nicknames, aliases). Attach documentation of all legal name changes. ☐ Not Applicable ☐ Other Names Used: _____			
Mailing Address:			
Birth Date:		**Contact Phone:**	
EMAIL AGREEMENT: By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.			
Email Address:		☐ Send my Correspondence by Email ☐ Send my Correspondence by US Mail	
SOCIAL SECURITY NUMBER: AS 08.01.060 requires you to provide your United States Social Security Number. It is considered confidential information and will not be publicly disclosed; it may be used to verify inter-state licensure.			

PART III Practice Information

Have you been in continuous practice for at least 6 months in another jurisdiction for each year your Alaska license was lapsed?

☐ **YES** ☐ **NO**

PART III Practice Information *Continued*

OTHER STATE LICENSES

List all jurisdictions which you hold or have held a license to practice pharmacy:

State or Jurisdiction	Licensed By: (Exam, Reciprocal, or other)	License #	Date of Issuance

PRACTICE HISTORY

Date Began: (mm/dd/yyyy)	Date Ended: (mm/dd/yyyy)	Employer Name	Employee Position	Employer Address

PART IV Continuing Education

If you are applying under 12 AAC 52.310(c) (license expired more than two years but not more than five years) you must submit copies of continuing education certificates verifying continuing education hours that would have been required to maintain a current license for the entire period your Alaska pharmacist license has been lapsed. Refer to attached regulations regarding continuing education requirements.

☐ **I have completed all hours of continuing education required.**

☐ **I have attached copies of all continuing education certificates of completion.**

PART V Professional Fitness Questions

The following professional fitness questions must be answered. "Yes" answers may not automatically result in license denial. If you answer "Yes" to any of the questions, please explain dates and specific circumstances (locations, type of action, organizations or parties involved) on a separate piece of paper, signed and dated, and send any supporting documents that are applicable (court records, judgments, charging documents, certificates of completion, board or license actions, investigative notices, etc.).

When in doubt, disclose and explain.

1. Have you ever had a professional license denied, revoked, suspended, or otherwise restricted, conditioned, or limited or have you surrendered a professional license, been fined, placed on probation reprimanded, disciplined, or entered into a settlement with a licensing authority in connection with a professional license you have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending?

☐ **Yes**
☐ **No**

2. Have you ever been convicted of a crime or are you currently charged with committing a crime? For purposes of this question, "crime" includes a misdemeanor, felony, or a military offense, including but not limited to, driving under the influence (DUI) or driving while intoxicated (DWI), driving without a license, reckless driving, or driving with a suspended or revoked license. "Convicted" includes having been found guilty by verdict of a judge or jury, having entered a plea of guilty, nolo contendere or no contest, or having been given probation, a suspended imposition of sentence, or a fine.

☐ **Yes**
☐ **No**

2.a. If yes, did any convictions include any of the following as listed under 12 AAC 52.925?

(1) murder;
(2) manslaughter;
(3) criminally negligent homicide;
(4) assault;
(5) sexual assault;
(6) sexual abuse of a minor;
(7) unlawful exploitation of a minor, including possession or distribution of child pornography;
(8) incest;
(9) indecent exposure;
(10) robbery;
(11) extortion;
(12) stalking;
(13) kidnapping;
(14) theft;
(15) burglary;
(16) forgery;
(17) endangering the welfare of a child;
(18) endangering the welfare of a vulnerable adult;
(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;
(20) reckless endangerment

3. Within the past five years, have you been or are you addicted to, excessively used, or misused alcohol, narcotics, barbiturates, or habit-forming drugs?

☐ **Yes ***
☐ **No**

4. Do you currently have a condition which in any way impairs or limits your ability to practice with reasonable skill and safety?

☐ **Yes ***
☐ **No**

THE STATE of ALASKA

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Notary Signature Page

Applicant Name:	

PART VI Notarized Signature

I hereby certify that I am the person herein named and subscribing to this application and that I have read the complete application, and I know the full content thereof. I declare that all of the information contained herein, and evidence or other documents submitted herewith are true and correct.

I understand that any falsification or misrepresentation of any item or response in this application, or any attachment hereto, or falsification or misrepresentation of documents to support this application, is sufficient grounds for denying, revoking, or otherwise disciplining a license or permit to practice in the state of Alaska.

I further understand that it is a Class A misdemeanor under Alaska Statute 11.56.210 to falsify an application and commit the crime of unsworn falsification.

A person who makes a false statement on this application may be subject to civil and criminal penalties, including prosecution for perjury (AS 11.56.200 & AS 11.56.230).

Notary Stamp

Applicant's Printed Name:			
Applicant's Signature:			
Notary Public for State of:		**Subscribed and Sworn to Before me on this Day:**	
Notary's Signature:		**My Commission Expires:**	

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Verification of Licensure

→ Applicant: Complete this top part and then forward a copy to all states, territories or other countries' licensing jurisdictions where you have ever been licensed. Make copies as needed.

Full Legal Name:		**License #:**	
Mailing Address:			
Applicant's Signature:		**Email:**	

→ State Board of: _____

Complete this bottom part for the applicant identified above and return the form directly to the letterhead address. You may use your state verification of license certificate if it includes all of the below information.

License Status:	☐ **Current** ☐ **Lapsed** ☐ **Expiry Date:** _____			
License Type:		**Issue Date:**		☐ Examination ☐ Reciprocity

Has this applicant's license ever been denied, revoked, suspended, surrendered, placed on probation, reprimanded, disciplined, or in any other manner limited by a licensing or disciplinary authority in your state? **Yes** ☐ **No** ☐

! If you answered "Yes" to the question above, please attach a detailed explanation or documentation signed and dated by the person whose signature appears below.

Board Seal	**Printed Name:**		
	Title:		
	Phone:	**Email:**	
	Signature:	**Date:**	

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Verification of Continuous Practice

→ **Applicant**: The top section must be completed by the applicant.

Applicant's Name:		**Phone #:**	
Applicant's Signature:		**Date:**	

Indicate whether you were in continuous practice for at least six (6) months for **each year** your AK license was in lapsed or expired status.
Date license lapsed or expired: _____ (mm/dd/yyyy)

Entry	Year	Employer	Jurisdiction	At least 6 months?
A				☐ **YES** ☐ **NO**
B				☐ **YES** ☐ **NO**
C				☐ **YES** ☐ **NO**
D				☐ **YES** ☐ **NO**

→ **Verifying Employer**: Verify practice by referring to the corresponding entry.

Entry A

I, _____, am verifying practice history for the above-named applicant for this time period.			
Signature:		**Date:**	

Entry B

I, _____, am verifying practice history for the above-named applicant for this time period.			
Signature:		**Date:**	

Entry C

I, _____, am verifying practice history for the above-named applicant for this time period.			
Signature:		**Date:**	

Entry D

I, _____, am verifying practice history for the above-named applicant for this time period.			
Signature:		**Date:**	

License Reinstatement & Continuing Education Requirements

12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE. (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

(1) submits a completed application for reinstatement on a form provided by the department;

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated

Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE. An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

12 AAC 52.340 APPROVED PROGRAMS. (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE;

(2) cardiopulmonary resuscitation (CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section, the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

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PO Box 110806, Juneau, AK 99811
Phone: (907) 465-2550

Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: _____

Program Type: _____ License Number *(if applicable)*: _____

I wish to make payment by credit card for the following *(check all that apply)*: **AMOUNT**

- ☐ Application Fee: _____ _____
- ☐ License or Renewal Fee: _____ _____
- ☐ Other *(name change, wall certificate, fine, duplicate license, exam, etc.)*:
  1. _____ _____
  2. _____ _____

TOTAL: _____

Name *(as shown on credit card)*: _____

Mailing Address: _____

Phone Number: _____ Email *(optional)*: _____

Signature of Credit Card Holder: _____

08-4438 Rev 12/26/18 Credit Card Payment Form (all major cards accepted)

CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!

1. Account Number: _____
2. Expiration Date: _____
3. Billing ZIP Code: _____
4. Security Code: _____

All four fields **MUST** be completed!

This section will be destroyed after the payment is processed

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Change of PIC/Facility Manager – *Incoming*

PHARMACIST-IN-CHARGE (PIC): Within 10 days of appointment as the new pharmacist-in-charge, you must notify the division in writing by completing this form.

CHANGE OF MANAGER FOR A WHOLESALE DISTRIBUTOR: Within 30 days of a change in facility manager, the new facility manager must submit a resume and completed fingerprint cards for evaluation and investigation by the Department of Public Safety. Request fingerprint cards at ***www.My.Alaska.Gov*** under the Professional License service link. *(12 AAC 52.610(d)(1)).*

CHANGE OF FACILITY MANAGER FOR AN OUTSOURCING FACILITY OR THIRD-PARTY LOGISTICS PROVIDER: Within 10 days of a change in facility manager, the new facility manager must submit a resume and completed fingerprint cards for evaluation and investigation by the Department of Public Safety. Request fingerprint cards at ***www.My.Alaska.Gov*** under the Professional License service link. *(12 AAC 52.696(c) and 12 AAC 52.697(c)).*

PART I Payment of Fees

Required Fees:	☐ Change of PIC/Facility Manager Certified check or money order payable to "State of Alaska."	**$5.00**

PART II Pharmacy/Facility Information

Name of Pharmacy/Facility:				
Alaska License or Registration Number:				
License Type:	☐ **Retail/Institutional** ☐ **Out-of-State Pharmacy** ☐ **In-State Pharmacy**	☐ **Drug Room** ☐ **Wholesale Drug Distributor (In-State)** ☐ **Wholesale Drug Distributor (Out-of-State)**	☐ **Outsourcing Facility** ☐ **Third-Party Logistics**	
New PIC/Facility Manager:		**Date of Appointment:**		
If PIC, License Number: **(If facility manager, write N/A)**		**State:**		

EMAIL AGREEMENT: By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.

Pharmacy/Facility Email:			
Previous PIC/Facility Manager:			
Signature:		**Date:**	

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Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: _____

Program Type: _____ License Number *(if applicable)*: _____

I wish to make payment by credit card for the following *(check all that apply)*: **AMOUNT**

- ☐ Application Fee: _____ _____
- ☐ License or Renewal Fee: _____ _____
- ☐ Other *(name change, wall certificate, fine, duplicate license, exam, etc.)*:
  1. _____ _____
  2. _____ _____

TOTAL: _____

Name *(as shown on credit card)*: _____

Mailing Address: _____

Phone Number: _____ Email *(optional)*: _____

Signature of Credit Card Holder: _____

08-4438 Rev 12/26/18 Credit Card Payment Form (all major cards accepted)

CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!

1. Account Number: _____
2. Expiration Date: _____
3. Billing ZIP Code: _____
4. Security Code: _____

All four fields **MUST** be completed!

This section will be destroyed after the payment is processed

Board of Pharmacy Task List
(Tasks from previous meetings: May 20-21, 2021)

Number of tasks assigned	Completed	Pending
34		

No.	Task	Assigned	Status
1	Ms. Carrillo will send the February 18-19, 2021 meeting minutes for signature and request it to be posted on the Board's meeting page.	Laura Carrillo	Completed 05/25/2021
2	Ms. Carrillo will send the signed imposition of civil fine and voluntary license surrender documents to Chair Holt for his signature then forward the signed documents to Investigator Bowles.	Laura Carrillo, Rich Holt	Completed 05/21/2021
3	Ms. Carrillo will create a draft matrix charting the most common types of reprimands on the different types of violations for further discussion at the September meeting.	Laura Carrillo	
4	Ms. Carrillo will look for the decision on fine amounts per hour of missed continuing education and will add it to the September meeting agenda.	Laura Carrillo	Heather found on 05/20/2021; Ms. Carrillo added materials to September meeting folder
5	Ms. Carrillo will retrieve a copy of the Medical Board's matrix and will provide it to the board at their next meeting in September.	Laura Carrillo	Added to packet 06/04/2021
6	Ms. Bell will touch base with Investigator Bowles to review the inspection process.	Lana Bell	
7	Ms. Carrillo will locate the inspection template markups from Chair Holt and will incorporate it into the September meeting materials.	Laura Carrillo	

8	All board members will be prepared to provide input on inspection report by the September meeting.	All	
9	Ms. Carrillo will provide the motion minutes to Ms. Noe for issuance of the wholesale drug distributor license for Blessings International, in-process #169542.	Laura Carrillo/ Heather Noe	Completed 05/28/2021
10	Ms. Carrillo will provide the motion minutes to Ms. Carlile for issuance of the pharmacy technician license for in-process #164543.	Laura Carrillo/ Bethany Carlile	Completed 05/28/2021
11	Ms. Carrillo will follow-up with the applicant for in-process #147445 requesting documents required to complete the application. The application will be placed on the September agenda.	Laura Carrillo	Completed 05/28/2021
12	Ms. Carrillo will follow-up with #PHAP1602 to communicate applicable timelines to proceed with the application. The application will be placed on the September agenda.	Laura Carrillo	Completed 05/28/2021; 09/29/2021 = abandoned 06/30/2023 = reinstatement eligibility ends
13	Ms. Carrillo will follow-up on the fingerprint fees for wholesale drug distributors, outsourcing facilities, and third-party logistics providers.	Laura Carrillo	Completed 05/28/2021
14	Ms. Carrillo will request a new page for the board's Strategic Plan to be created with the 2021 plan uploaded to it.	Laura Carrillo	Initiated 05/28/2021; Completed 06/14/2021
15	Ms. Carrillo will work on the draft 2022 plan for review and discussion at the board's September meeting.	Laura Carrillo	Completed 09/09/2021
16	Ms. Carrillo will add in budgetary recommendations to the 2021 Annual Report for conference travel and training, including the NABP annual report and district meetings, MPJE workshops, compounding conferences, and the Rx Summit.	Laura Carrillo	Completed 05/27/2021

17	Ms. Carrillo will finalize the 2021 Annual Report and submit it to the board for review and approval.	Laura Carrillo	Initiated 05/27/2021; with edits 05/28/2021; Completed on 08/09/2021
18	Ms. Carrillo will follow-up with the Board of Nursing on their plan to address the board's letter at their next meeting in August.	Laura Carrillo	Initiated 11/18/2020; follow-up 12/08/2020, 01/25/2021, 04/06/2021, 05/28/2021
19	Ms. Carrillo will poll the board for available meeting dates in May and September.	Laura Carrillo	Completed; May date for 20-21; Sept date 23-24
20	Ms. Carrillo will follow-up on expectations for CSAC administrative duties.	Laura Carrillo	Initiated 06/01/2021
21	Ms. Carrillo will update the board's Authorized Emergency Courtesy License Activities document to provide an end date and will request to take down the courtesy license application on June 30.	Laura Carrillo	Initiated 06/01/2021; Completed 07/07/2021
22	Ms. Carrillo will inquire with the regulations specialist whether it is possible to include most recent regulatory markups in published statutes and regulations.	Laura Carrillo	Completed 06/02/2021
23	Ms. Carrillo will plan to attend the staff NABP training on June 15th.	Laura Carrillo	-
24	Chair Holt will put language together addressing expiration dates into 12 AAC 52.480 for the board's consideration at their next meeting in September.	Rich Holt	-
25	Ms. Carrillo will create a draft notification form acknowledging discrepancies of an inspection and will present it to the board at their September meeting.	Laura Carrillo	Completed 06/04/2021
26	Ms. Carrillo will look into the cost of the inspections if the board were to do 10-15 inspections and will add this into the board's annual report.	Laura Carrillo	Completed 05/28/2021
27	Ms. Carrillo will clarify with the prescribing board chairs that AS	Laura Carrillo	Completed 05/26/2021

	17.30.200(t) requires prescriptions written for more than a 24-hour supply to be reported.		
28	Ms. Carrillo will forward the approved PDMP regulation amendments to the regulations specialist to request cursory review by the Department of Law and will append the changes to the minutes.	Laura Carrillo	Completed 06/04/2021
29	Ms. Carrillo will update the board's PDMP disciplinary matrix to reflect daily tracking of reporting compliance for monthly referrals to the Investigative Unit.	Laura Carrillo	Initiated 06/04/2021
30	Laura will draft letter of new plan and will send the notice to the board for review/approval with the aim to mail it out on June 1st.	Laura Carrillo	Initiated 06/04/2021
31	Ms. Carrillo will follow up with EA Norberg on the Medical Board's discussion of the joint cooperative practice agreement plan.	Laura Carrillo	Initiated 06/04/2021
32	Ms. Carrillo will follow-up with the Board of Nursing, Board of Dental Examiners, and Board of Examiners in Optometry on their intent to pursue similar cooperative practice agreement regulations.	Laura Carrillo	Initiated 06/04/2021
33	Ms. Bell will provide language to Ms. Carrillo on a potential request to DOL regarding IHS pharmacists and collaborative practice agreements.	Lana Bell	
34	Ms. Carrillo will submit travel requests for the September and November meetings in Anchorage and February 2022 meeting in Juneau.	Laura Carrillo	Submitted November request 09/08/2021

Ongoing previous tasks:

From Feb. 18-19, 2021 meeting	Dr. Ruffridge will review the website FAQs for accuracy and applicability and recommend at the board's next meeting what FAQs need to be added, updated, removed, or turned into position statements.	Justin Ruffridge	Is 1/4th complete as of May 20-21 meeting;
From Feb. 18-19, 2021 meeting	All board members will review the investigative checklist and sample letter in advance of the May meeting	All	By September 2021 meeting

STATUTES/ REGULATIONS

Statutes and Regulations
Pharmacy

May 2021

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Rev. 5/14/2021

TABLE OF CONTENTS

CHAPTER 80. PHARMACISTS AND PHARMACIES

Article

ARTICLE 1. THE BOARD OF PHARMACY

Section

Sec. 08.80.003. PRACTICE OF PHARMACY AS A PROFESSION. The practice of pharmacy is declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest that only qualified persons be permitted to engage in the practice of pharmacy, and to ensure the quality of drugs and related devices distributed in the state.

Sec. 08.80.005. STATEMENT OF PURPOSE. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Sec. 08.80.010. CREATION AND MEMBERSHIP OF BOARD; OFFICERS. (a) There is created the Board of Pharmacy, composed of seven members, five of whom shall be pharmacists licensed in the state who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. Two shall be persons with no direct financial interest in the health care industry. Whenever possible, the board shall include at least one member from each judicial district.

(b) An officer elected by the board serves a term of one year and may not serve more than four consecutive full terms in a specific office.

Sec. 08.80.020. Term of office. *[Repealed, Sec. 20 ch 80 SLA 1996.]*

Sec. 08.80.030. POWERS AND DUTIES OF THE BOARD. (a) The board is responsible for the control and regulation of the practice of pharmacy.

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business;

(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

(c) The board shall post and maintain a link to the United States Food and Drug Administration's list of all currently approved interchangeable biological products on the board's Internet website.

(d) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

Sec. 08.80.040. Duties of the board. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.045. NONPRESCRIPTION DRUGS. (a) Except as provided in (b) of this section the board may not regulate the sale of patent or nonprescription drugs that are prepackaged for use by the consumer, are in their original, unbroken packaging, and are labeled in accordance with requirements of the federal government.

(b) The board may regulate the sale and distribution of patent or nonprescription drugs under AS 44.62.250 when the regulation is required by an emergency to protect the public health and safety.

Sec. 08.80.050. APPLICABILITY OF ADMINISTRATIVE PROCEDURE ACT. The board shall comply with AS 44.62 (Administrative Procedure Act).

Sec. 08.80.060. MEETINGS OF THE BOARD. The board shall meet at least three times each year at the call of the president for the transaction of business properly before it. The president shall also call the board into session when requested in writing by at least two members. Meetings may be held telephonically.

Sec. 08.80.070. QUORUM. Four members constitute a quorum for the transaction of business. However, when the board meets for the purpose of examining applications for licensure, three members of the board constitute a quorum.

Sec. 08.80.080. EXPENSES OF MEMBERS. Members of the board are entitled to reimbursement for actual travel expenses incidental to the discharge of their duties and, while in the performance of their duties, are entitled to the per diem expenses allowed by law.

Sec. 08.80.090. Disposition of fees. *[Repealed, Sec. 54 ch 37 SLA 1985.]*

Sec. 08.80.100. Board secretary as certifying officer. *[Repealed, Sec. 3 ch 59 SLA 1966.]*

Sec. 08.80.105. REMOVAL OF BOARD MEMBERS. A member of the board may be removed from office by the governor for cause.

ARTICLE 2. LICENSING AND REGISTRATION

Section

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall

(1) be fluent in the reading, writing, and speaking of the English language;

(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(3) be a graduate of a college in a degree program approved by the board;

(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;

(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.115. Registration of pregraduate and postgraduate intern pharmacist. *[Repealed, Sec. 40 ch 177 SLA 1978.]*

Sec. 08.80.116. INTERNSHIP AND OTHER TRAINING PROGRAMS. (a) An applicant for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under terms and conditions the board shall determine.

(b) The board shall establish licensure requirements for interns and standards for internship or other training programs that are necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

Sec. 08.80.117. Malpractice insurance. *[Repealed, Sec. 7 ch 94 SLA 1980.]*

Sec. 08.80.120. GRADING AND CONTENT OF EXAMINATION. The examination or examinations shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with an organization or consultant in the preparation and grading of an examination, but shall retain sole discretion and responsibility for determining which applicants have successfully passed the examinations.

Sec. 08.80.130. Reexamination. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.140. License by credentials. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

(1) submits a written application to the board on a form required by the board;

(2) is at least 18 years of age;

(3) is of good moral character;

(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;

(5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

Sec. 08.80.150. TEMPORARY LICENSE. The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

Sec. 08.80.155. EMERGENCY PERMIT. The board shall adopt regulations regarding the issuance of an emergency permit to practice pharmacy.

Sec. 08.80.157. LICENSING OF FACILITIES. (a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390.

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

(k) This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription drugs to consumers in the state shall register with the board.

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; and

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

(c) A pharmacy subject to this section shall, during its regular hours of operations, provide a toll-free telephone service to facilitate communication between persons in the state and a pharmacist at the pharmacy who has access to records concerning the dispensing of prescription drugs to persons in the state. The toll-free number and the hours that the service is available shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state. The telephone service shall be available at least 40 hours a week and at least six days a week.

(d) The board may, after a hearing, deny, revoke, or suspend the registration of a pharmacy located outside of the state and subject to this section if the pharmacy fails to comply with the requirements of this section, AS 17.20.080 - AS 17.20.135, or AS 17.30.020 - 17.30.080, or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

(e) A pharmacy located outside of the state that is subject to this section but is not registered with the board under this section may not ship, mail, or deliver prescription drugs into the state and may not advertise its services in the state.

(f) A pharmacy subject to this section shall appoint a registered agent in the state who is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent under this subsection, if the registered agent cannot with reasonable diligence be found at the registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner of commerce and economic development is an agent upon whom process, notice, or demand may be served. Service is made upon the commissioner in the same manner as provided for corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

(g) The board shall by regulation define “regularly” for this section.

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;

(2) appoint an agent on whom process can be served in the state; and

(3) authorize inspection of the facility by a designee of the board under (c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

(1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

(1) require an inspection of the applicant's facility located outside the state; and

(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;

(2) reexamination;

(3) investigation for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) registration or licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS. The board shall establish requirements for continuing education in pharmacy that must be satisfied before a license issued under this chapter may be renewed.

Sec. 08.80.168. ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.

(a) A pharmacist may independently administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(b) A pharmacist may independently dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(c) In this section,

(1) "opioid overdose drug" has the meaning given in AS 17.20.085;

(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

Sec. 08.80.170-08.80.210. Fees. *[Repealed, Sec. 7 ch 24 SLA 1968.]*

Sec. 08.220. Prescription department required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.230. Sanitary conditions required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.240. Form and display of registration certificate and license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.250-08.80.260. Renewal of lapsed registration; ground for refusing or revoking a license. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.261. DISCIPLINARY SANCTIONS. (a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable,

(1) secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or a drug that impairs the applicant's or licensee's ability to practice safely;

(D) physical or mental disability; or

(E) other factors determined by the board;

(8) engaged in conduct involving moral turpitude or gross immorality;

(9) made a controlled substance available to a person except upon prescription issued by a person licensed to prescribe controlled substances;

(10) was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(12) failed to report relevant information to the board about a pharmacist or pharmacy intern that the applicant or licensee knew or suspected was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(13) aided another person to engage in the practice of pharmacy or to use the title of "pharmacist" or "pharmacy intern" without a license; or

(14) engaged in unprofessional conduct, as defined in regulations of the board.

(b) The board may place under seal all drugs that are owned by or in the possession, custody, or control of a licensee at the time a license is suspended or revoked or at the time the board refuses to renew a license. Except for perishable items, the drugs may not be disposed of until the licensee has exhausted administrative and judicial remedies relating to the licensing action. Perishable items may be sold upon order of the court with the proceeds to be deposited with the court. The board shall notify the Department of Health and Social Services about drugs placed under seal under this subsection.

Sec. 08.80.265. Limits or conditions on license; discipline. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.266. Disciplinary sanctions. *[Repealed, Sec. 49 ch 94 SLA 1987.]*

Sec. 08.80.270. EXECUTIVE ADMINISTRATOR OF THE BOARD. (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS

39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

ARTICLE 3. DUTIES OF LICENSED PHARMACISTS

Section

Sec. 08.80.270-08.80.290. Report of employees and goods sold; affixing labels. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.294. INFORMATION ABOUT EQUIVALENT GENERIC DRUGS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed;

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS OR INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product.

(b) A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing practitioner through

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;

(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);

(C) a plan offered under AS 39.30.090 or 39.30.091;

(D) a federal governmental plan as defined under AS 21.54.500;

(E) the Medicaid or Medicare program; or

(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

Sec. 08.80.300. Record of prescriptions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.310. Record of sales. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained by a pharmacist in the patient's records or that is communicated to the patient as part of patient counseling is confidential and may be released only to

(1) the patient or as the patient directs;

(2) a practitioner or pharmacist when, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well-being; and

(3) other persons or governmental agencies authorized by law to receive confidential information.

Sec. 08.80.320. Pharmacist required. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS "PHARMACIST-IN-CHARGE". (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

Sec. 08.80.335. PRESCRIPTION FOR AN OPIOID; VOLUNTARY REQUEST FOR LESSER QUANTITY. (a) A pharmacist filling a prescription for an opioid that is a schedule II or III controlled substance under federal law may, at the request of the individual for whom the prescription is written, dispense the prescribed opioid in a lesser quantity than prescribed.

(b) Nothing in this section shall be construed to prevent substitution of an equivalent drug under AS 08.80.295.

Sec. 08.80.340-08.80.370. Requirements for handling drugs; general prohibitions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

ARTICLE 4. UNLAWFUL ACTS

Section

Sec. 08.80.380 Issuance of shopkeepers permits. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that provides dispensing of drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED. A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

Sec. 08.80.440. Denial of examination or license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

Sec. 08.80.460. PENALTIES. (a) Except for a violation of AS 08.80.297, a person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 or 08.80.297 may be punished by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

ARTICLE 5. GENERAL PROVISIONS

Section

Sec. 08.80.470. CONSTRUCTION. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.20 (the Alaska Food, Drug and Cosmetic Act), or AS 17.30.

Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(3) "board" means the Board of Pharmacy;

(4) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(5) "controlled substance" has the meaning given in AS 11.71.900;

(6) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(7) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(9) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(10) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(11) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug, drug-food, and drug-disease interactions;

(G) adverse drug reactions; and

(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(13) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(14) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(15) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor or a nonprescription drug or commercially packed legend drug or device;

(16) "legend drug" means a prescription drug;

(17) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(18) “nonprescription drug” means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(19) “outpatient dispensing” means dispensing drugs for administration outside of the hospital pharmacy’s control;

(20) “outsourcing facility” means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location;

(21) “owner” means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(22) “patient counseling” means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(23) “person” has the meaning given in AS 01.10.060 and also includes a governmental agency;

(24) “pharmaceutical care” is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(25) “pharmacist” means an individual currently licensed by this state to engage in the practice of pharmacy;

(26) “pharmacist-in-charge” means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy’s personnel;

(27) “pharmacy” means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157(b);

(28) “pharmacy located outside of the state” means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(29) “pharmacy technician” means a supportive staff member who works under the immediate supervision of a pharmacist;

(30) “practice of pharmacy” means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the administration of vaccines and related emergency medication; the independent dispensing of opioid overdose drugs; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

(31) “practitioner” means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(32) “preceptor” means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(33) “prescription drug” means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) “Caution: Federal law prohibits dispensing without prescription”; (B) “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(34) “prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient;

(35) “prospective drug use review” means a review of the patient’s drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(36) “significant adverse drug reaction” means a drug-related incident that may result in serious harm, injury, or death to the patient;

(37) “substitute” means to dispense, without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug; or

(B) an interchangeable biological product in place of the prescribed biological product;

(38) “third-party logistics provider” means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

(39) “wholesale” means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(40) “wholesale drug distributor” means anyone engaged in wholesale distribution of drugs, including manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Sec. 08.80.490. SHORT TITLE. This chapter may be known as the Pharmacy Act.

CHAPTER 52.
BOARD OF PHARMACY.

Article

ARTICLE 1.
LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

Section

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE. (a) The board will issue the following categories of licenses or permits to a qualified individual:

(1) pharmacist license;
(2) temporary pharmacist license;
(3) emergency permit to practice pharmacy;
(4) pharmacist intern license;
(5) pharmacy technician license.

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

(1) pharmacy license;
(2) repealed 2/26/2000;
(3) wholesale drug distributor license;
(4) drug room license;
(5) registration of a pharmacy located outside of the state;
(6) remote pharmacy license;

(7) third-party logistics provider license;
(8) outsourcing facility license;
(9) license of a wholesale drug distributor located outside of the state.

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158
AS 08.80.030 AS 08.80.155 AS 08.80.159
AS 08.80.116 AS 08.80.157 AS 08.80.390

12 AAC 52.020. FACILITY LICENSE. (a) An applicant for a facility license shall submit
(1) the fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (a) The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall
(1) submit a new, completed application for a pharmacy license; and
(2) pay the duplicate license fee required in 12 AAC 02.105;
(3) repealed 1/17/2007.
(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (a) Repealed 1/17/2007.
(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.050. CLOSED PHARMACIES. (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall
(1) submit written notice to the board of the cessation of pharmacy operations on a form provided by the department; the form must be submitted within 10 days after the cessation of operations and include
(A) the date the pharmacy ceased operations;
(B) a statement signed by the pharmacist-in-charge attesting that an inventory of all controlled substances on hand has been conducted; and
(C) a statement signed by the pharmacist-in-charge attesting to the manner of disposition for all prescription drugs possessed by the pharmacy;
(2) arrange for the transfer of prescription drug orders or computer prescription records to another pharmacy to facilitate continuous patient care; and
(3) provide for the maintenance and availability of prescription drug orders or hard copies of computer prescription records in accordance with 12 AAC 52.450(a) that are not transferred to another pharmacy;
(4) repealed 1/17/2007.
(b) In the absence of a pharmacist-in-charge, the owner of the pharmacy shall meet all requirements of this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.060. FIRE OR OTHER DISASTER. (a) If a pharmacy has a fire or other disaster, the pharmacist-in-charge of the pharmacy shall

(1) within 10 days, report to the board the date of a fire or any disaster that may affect the strength, purity, or labeling of drugs, devices, or other materials used in the practice of the pharmacy;

(2) provide the board with a copy of a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances," reporting the loss or destruction of controlled substances or DEA order forms; if the extent of the loss of controlled substances cannot be determined, the pharmacist-in-charge shall submit to the board a complete inventory of all remaining controlled substances and a statement, signed by the pharmacist-in-charge, attesting to the accuracy of the inventory; and

(3) notify the board in writing within 10 days after any change in the pharmacy's address, including a move to a temporary location or a return to the pharmacy's permanent location.

(b) If a pharmacy maintains a temporary location for more than 90 days, the pharmacist-in-charge of the pharmacy shall apply for a new and separate facility license as required in 12 AAC 52.030.

(c) A pharmacy may not dispense any drug that has been exposed to excessive heat, smoke, or other conditions that may have caused deterioration.

(d) In this section, "other disaster" includes any disaster situation that causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (a) An applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by examination.

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080, sent directly to the department from the agency where the hours of internship or experience were completed;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

12 AAC 52.075. GOOD MORAL CHARACTER. As used in AS 08.80, "good moral character" includes not having been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.

(c) Repealed 4/16/2016.

(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION. (a) In addition to the requirements in AS 08.80.110, an applicant for a pharmacist license shall pass the

(1) North American Pharmacy licensing examination (NAPLEX) administered by the National Association of Boards of Pharmacy with a NAPLEX scaled score of 75 or above; and

(2) Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(b) An applicant for a temporary pharmacist license shall pass the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(c) An applicant for a pharmacist license that has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of examination scores directly to the department.

(d) An applicant for licensure by examination must submit an application under 12 AAC 52.070 and be approved under 12 AAC 52.092 before sitting for examination under this section.

(e) An applicant who has failed the Alaska pharmacy jurisprudence examination specified in (f) of this section may not retake the examination for at least 30 days.

(f) The Multistate Pharmacy Jurisprudence Examination administered by the National Association of Boards of Pharmacy (NABP) is the examination adopted by the board as the Alaska pharmacy jurisprudence examination. An applicant shall satisfy all other license requirements within one year after passing the Alaska pharmacy jurisprudence examination or retake the examination.

(g) An applicant applying for a pharmacy license by examination shall make application within one year of successfully passing the NAPLEX. An applicant applying more than one year after passing the NAPLEX shall retake the NAPLEX or apply for a pharmacy license under AS 08.80.145.

Authority: AS 08.01.065 AS 08.80.110 AS 08.80.150
AS 08.80.005 AS 08.80.120 AS 08.80.160
AS 08.80.030

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements set out in (c) of this section has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity.

(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.

(c) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080; the verification must be sent directly to the department from the agency where the hours of internship or experience were completed; or

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) verification that the applicant is currently licensed as a pharmacist in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy;

(10) verification of the present status of the applicant's license in each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist.

(d) An applicant for licensure under this section who has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (c)(1) – (6) and (8) – (10) of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.100. TEMPORARY PHARMACIST LICENSE. (a) The board will issue a temporary pharmacist license to an applicant for licensure if the applicant

(1) submits a completed application for licensure;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) repealed 2/26/2000;

(4) provides for the National Association of Boards of Pharmacy (NABP) to notify the board that the applicant has submitted a preliminary application to NABP for license transfer;

(5) pays the application fee, pharmacist license fee, and temporary license fee required in 12 AAC 02.310;

(6) passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above;

(7) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely; and

(8) submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

(b) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, the board will extend the temporary license for an additional period not to exceed 60 days.

(d) A temporary license is not renewable.

(e) An individual may not receive more than one temporary license.

Authority: AS 08.80.005 AS 08.80.145 AS 08.80.150
AS 08.80.030

12 AAC 52.110. EMERGENCY LICENSURE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN. (a) If the board determines that an emergency exists requiring the provision of licensed coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, the board may issue an emergency pharmacist, pharmacy intern, or pharmacy technician permit to an applicant who

(1) submits a completed application on a form provided by the department;

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits verification on a form provided by the department that the applicant is currently licensed in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(4) repealed 10/31/2019; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit under (a) of this section is nonrenewable, and is valid for 90 days or until the emergency circumstances no longer exist, whichever is shorter.

(c) Repealed 11/19/2020.

(d) In an urgent situation, the board may issue an emergency courtesy license to practice as a pharmacist, pharmacy intern, or pharmacy technician to an applicant who meets the requirements of this section. The board may restrict the license to only those services required to respond to the urgent situation. The licensee may not practice as a pharmacist, pharmacy intern, or pharmacy technician outside the scope of the limited purpose for which the emergency courtesy license is issued.

(e) An applicant for an emergency courtesy license under this section must submit to the department a completed application on a form provided by the department. A complete application includes the applicable application and licensing fees established in 12 AAC 02.105.

(f) An emergency courtesy license issued under this section is valid for the period specified by the board and may not exceed 120 consecutive days. An emergency courtesy license may be renewed for one additional period specified by the board, not to exceed 120 consecutive days.

(g) The board will not issue, and an emergency courtesy license holder may not use, an emergency courtesy license as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency courtesy license issued under this section, the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns, or pharmacy technicians.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the application fee and the pharmacist intern license fee established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act); and

(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) and (2) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state;

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an out-of-state pharmacy registration. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive an out-of-state pharmacy registration will not be issued a registration unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that registration.

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(1) applies on an application provided by the department that includes

(A) the company name and owner name;

(B) the pharmacy name;

(C) the location of the facility;

(D) a mailing address and telephone number;

(E) a toll free number accessible by patients in this state;

(F) the federal employer identification number;

(G) the names of all partners or corporate officers;

(H) the name, address, and telephone number for pharmacist-in-charge;

(I) the names of all pharmacists working in the facility;

(J) completion of the professional fitness section of the application; and

(K) the name of the appointed registered agent;

(2) pays the application fee and the out-of-state pharmacy registration fee established in 12 AAC 02.310;

(3) submits a certified true copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an inspection report or self-inspection report completed within the last two years.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140. PHARMACY TECHNICIAN LICENSE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacy technician license will not be

issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacy technician license.

(b) The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including

(A) the applicant's name, mailing address, and telephone number; and

(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310.

(c) A pharmacy technician license expires on June 30 of even-numbered years and may be renewed.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.150. PROOF OF LICENSURE FOR INDIVIDUAL PHARMACISTS WORKING FOR TRIBAL HEALTH PROGRAMS. (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(A) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450 – 458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(B) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to non-tribal health programs. In addition, an out-of-state licensed pharmacist working outside the scope of the individual's contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80.

Authority: AS 08.80.003 AS 08.80.005 AS 08.80.030

ARTICLE 2.
PERSONNEL.

Section

12 AAC 52.200. PHARMACIST-IN-CHARGE. (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 02.105(3).

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.160 AS 08.80.330

12 AAC 52.210. PHARMACIST DUTIES. Except as provided in 12 AAC 52.220 and 12 AAC 52.235, the following duties may be performed only by a pharmacist:

(1) receiving an oral prescription drug order from a practitioner or authorized agent of a practitioner;

(2) consulting with a prescriber regarding a patient or prescription;

(3) interpreting a prescription drug order;

(4) determining the product required for a prescription;

(5) interpreting data in a patient medication record system;

(6) assuming the responsibility for a filled prescription;

(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and

(8) administering a prescription drug order in accordance with the practitioner's order.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.220. PHARMACIST INTERNS. (a) A pharmacist intern may not represent that the pharmacist intern is a pharmacist. Only a person licensed by the board as a pharmacist intern may take, use, or exhibit the title of pharmacist intern or any other similar term.

(b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

(c) A pharmacist intern may not sign or initial any document that is required to be signed or initialed by a pharmacist unless the supervising pharmacist also signs or initials the document.

(d) A pharmacist intern shall file with the board a report of work experience on a form provided by the department within 30 days of completion or termination of an internship in the practice of pharmacy required under 12 AAC 52.080.

(e) A pharmacist supervising a pharmacist intern

(1) must be licensed as a pharmacist and be in good standing with the board;

(2) shall provide direct supervision to an intern during professional activities throughout the entire period of the internship;

(3) repealed 4/3/2020;

(4) is responsible for the work of the pharmacist intern;

(5) may supervise more than one pharmacist intern; more than one pharmacist intern may not dispense simultaneously under the direct supervision of the same supervising pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110 AS 08.80.116 AS 08.80.410

12 AAC 52.230. PHARMACY TECHNICIANS. (a) The following persons must be licensed as a pharmacy technician:

(1) an individual who assists in performing manipulative, nondiscretionary functions associated with the practice of pharmacy; and

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.

(b) A pharmacy technician shall work under the direct supervision of a person who is licensed as a pharmacist.

(c) Except as provided in 12 AAC 52.235, a pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

(d) An individual working as a pharmacy technician shall wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.

(e) Before an individual may regularly perform the tasks of a pharmacy technician, the individual shall complete training required by the pharmacist-in-charge. Duties performed by the pharmacy technician must be consistent with the training the pharmacy technician has received.

(f) If a pharmacy technician will assist in the preparation of sterile pharmaceuticals, including parenteral medications, the pharmacy technician must have completed a minimum of 40 hours of on-the-job training in the preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform those tasks.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.235. PHARMACY TECHNICIAN WITH NATIONAL CERTIFICATION. (a) A pharmacy technician who holds a national certification may, at the direction of the pharmacist on duty and under the direct supervision of that pharmacist,

(1) perform a final check of and distribute a non-controlled substance prescription if

(A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination of substitution;

(B) the pharmacy uses a bar code scanning and verification system that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label;

(C) the pharmacy uses software that displays the image or graphical description of the correct drug being verified; however, if there is any deviation between the image or graphical description and the actual product being distributed, a pharmacist must review and dispense the order; and

(D) each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500; or

(3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.

(b) Prescription drug order information clarifications under (a)(3) of this section must have the following information documented on the prescription drug order:

(1) the result of the clarification;

(2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the practitioner or authorized agent that the pharmacy technician spoke to; and

(4) the date of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

(d) In this section, "bar code scanning and verification system" means any technology that scans the bar code on a manufacturer drug container to ensure that the product being distributed matches the expectation of what was prescribed and inputted into the dispensing software.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;

(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and

(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;

(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months;

(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol;

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

(h) This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(i) A signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.250. JOB SHADOWING IN PHARMACY. (a) A pharmacist-in-charge or job shadowing preceptor of a pharmacy may allow job shadowing by a student in the pharmacy only as specified in this section.

(b) Before a student begins a job shadowing program under this section, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board, which includes the names of the pharmacy, the participating student, and the pharmacist-in-charge or job shadowing preceptor. The student and the pharmacist-in-charge or preceptor, shall sign the form. The parent or guardian of the student shall also sign the form if the student is less than 18 years of age.

(c) The pharmacist-in-charge or, if applicable, the job shadowing preceptor shall familiarize the student with the confidentiality requirements of 45 C.F.R., Parts 160 and 164 (HIPAA) and ensure compliance with this section and the relevant sections of AS 08.80 and this chapter.

(d) A pharmacist-in-charge or job shadowing preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than 50 hours;

(C) perform any functions reserved for licensed, certified, or registered pharmacy personnel;

(2) a ratio of job shadowing student to pharmacist-in-charge or job shadowing preceptor other than one to one.

(e) After completion of the job shadowing program by a student, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board where the pharmacist-in-charge or job shadowing preceptor provides the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The job shadowing documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed by that student.

(f) In this section,

(1) "job shadowing" means for educational purposes and through observation only, the observation by a student of the functions and duties of a pharmacy and pharmacy staff with the intended purpose of giving the student an opportunity to observe career possibilities available in the field of pharmacy;

(2) "job shadowing preceptor" means a licensed pharmacist, other than the pharmacist-in-charge, designated by the pharmacist-in-charge to supervise a student while that student is job shadowing;

(3) "student" means a person currently enrolled in a high school or post-secondary education program.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

Editor's note: The job shadowing documentation form required by 12 AAC 52.250 may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, P.O. Box 110806, Juneau, AK 99811-0806; phone: (907) 465-2589; or the division's website at http://www.commerce.state.ak.us/occ/ppha.htm.

ARTICLE 3.
LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS.

Section

12 AAC 52.300. LICENSE RENEWAL. (a) Pharmacy, wholesale drug distributor, and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license shall submit

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) a completed self-inspection of the premises questionnaire on a form provided by the department.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE. (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

(1) submits a completed application for reinstatement on a form provided by the department;

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005 AS 08.80.147

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacy technician license shall certify that, during the concluding licensing period, the applicant

(1) completed 10 contact hours of continuing education accepted by the board under 12 AAC 52.340; or

(2) obtained initial certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB).

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) Instead of complying with the continuing education requirements in (a) of this section, an applicant for renewal of a pharmacy technician license for the first time may

(1) verify in an affidavit, on an application for renewal, that the applicant has read the state statutes and regulations compiled by the board; and

(2) submit an affidavit, signed by the pharmacist-in-charge, verifying the applicant's pharmacy technician training in accordance with 12 AAC 52.230.

(d) An applicant for reinstatement of a pharmacy technician license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005

Editor's note: Information regarding certification with the Pharmacy Technician Certification Board described in 12 AAC 52.325 may be obtained from the Pharmacy Technician Certification Board, 1100 15th Street, NW, Suite 703, Washington, DC 20005-1707, phone: (202) 429-4120 or at PTCB's website at www.ptcb.org. The Alaska Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE. An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.165

12 AAC 52.340 APPROVED PROGRAMS. (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE that results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section,

the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

Authority: AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

ARTICLE 4.
GUIDELINES FOR PHARMACIES AND PHARMACISTS.

Section

12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, "*Facility Standards for Pharmacies,*" dated November 2016, and incorporated by reference in this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES. (a) A drug or device that has exceeded its expiration date shall be removed from stock and quarantined until properly disposed of in accordance with 12 AAC 52.560.

(b) A pharmacist may not dispense a drug or device beyond the expiration date on the drug or device.

(c) All drugs and devices on shelves or display for sale shall be protected against contamination, deterioration, and adulteration.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.420. SECURITY. (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department security requirements.

(c) All drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) The prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) Prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

(g) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

12 AAC 52.423. REMOTE PHARMACY LICENSE. (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

(1) it is able to comply with the requirements of 12 AAC 52.425; and

(2) there is no access to a non-remote pharmacy within ten road miles of the proposed remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles.

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. (a) Only a pharmacist employed by a central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state. The pharmacist-in-charge of a remote pharmacy may supervise one or more remote pharmacies.

(b) Before a pharmacist employed by a central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

(1) still image capture;

(2) real time link;

(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and

(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy from the central pharmacy or a wholesale distributor. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must have access to the records of the prescriptions dispensed by the remote pharmacy.

(g) The prescription label of a prescription drug dispensed by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the remote pharmacy. A prescription drug may not be dispensed by a remote pharmacy until a pharmacist employed by the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and

(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

(j) Repealed 10/31/2019.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.430. GUIDELINES RELATING TO STERILE PHARMACEUTICALS. A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the guidelines established by the board in the pamphlet titled, "*Sterile Pharmaceuticals,"* dated February 2008, and incorporated by reference in this section.

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.430, *"Sterile Pharmaceuticals"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES. A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "*Compounding Practices,"* dated February 2008, and incorporated by reference in this section

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.440, *"Compounding Practices"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY. (a) A requesting pharmacy in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacy to participate in shared pharmacy services if the pharmacy establishes

(1) that the pharmacy has a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) that the pharmacy is able to comply with the requirements of 12 AAC 52.445;

(3) that the pharmacy either

(A) is owned by the same owner as the filling pharmacy with which pharmacy services are to be shared; or

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligation of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(4) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. (a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacist to participate in shared pharmacy services if the requesting pharmacist establishes

(1) that the pharmacist

(A) has a current in-state pharmacy license issued under AS 08.80 and this chapter;

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligations of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(C) is able to comply with the requirements of 12 AAC 52.445; and

(2) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.445. SHARED PHARMACY SERVICES. (a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.

(b) Except as provided in (c) of this section, if a filling pharmacy or filling pharmacist delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist shall provide, on the prescription container or on a separate sheet delivered with the prescription container,

(1) the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist; and

(2) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."

(c) The requirements of (b) of this section do not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(d) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled, or dispensed, the name, initials, or identification code of each pharmacist responsible for the final verification of dispensing; those records must include descriptions of actions taken in interpretation of the order, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, and refill authorization functions performed at that pharmacy or by that pharmacist;

(2) report to the board as soon as practical the results of any license disciplinary action taken by a regulatory agency in another licensing jurisdiction involving a pharmacy or pharmacist participating in shared pharmacy services;

(3) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy or by that pharmacist;

(4) provide for adequate security to protect the confidentiality and integrity of patient information;

(5) provide for inspection of any required record or information no later than 72 hours after any request by the board or its designee.

(e) Each pharmacy participating in shared pharmacy services, if a

(1) requesting pharmacy, shall have a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) filling pharmacy, shall either

(A) have a current in-state pharmacy license issued under AS 08.80.157 and this chapter; or

(B) be registered as an out-of-state pharmacy under AS 08.80.158 and this chapter.

(f) Each participant in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Each participant is required to maintain only those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures must

(1) outline the responsibilities of each participant;

(2) include a list that contains

(A) each pharmacy participating in shared pharmacy services, and each pharmacist acting independently of a pharmacy and participating in shared pharmacy services;

(B) the name, address, and telephone number of each of those participants; and

(C) the license numbers for all licenses held by each of those participants; and

(3) address

(A) patient notification that meets the requirements of this section;

(B) the adequate protection of the confidentiality and integrity of patient information;

(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;

(D) the maintenance of manual or electronic records that meet the requirements of this section;

(E) compliance with federal and state laws; and

(F) the operation of a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(g) Nothing in this section prevents an individual pharmacist licensed in this state who is employed by or working under a contract with a pharmacy, or prevents a licensed pharmacy intern or pharmacy technician working under the supervision of that licensed pharmacist, from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription order in compliance with AS 08.80 and this chapter if

(1) the pharmacy has established controls to protect the privacy and security of confidential records; and

(2) the pharmacist, pharmacy intern, or pharmacy technician does not duplicate, download, or remove data from the pharmacy's electronic database.

(h) A pharmacist working independently outside of the state may participate in shared pharmacy services with an institutional pharmacy in this state if the pharmacist holds

(1) a current license as a pharmacist issued under AS 08.80 and this chapter; and

(2) a current license to practice as a pharmacist issued by the licensing jurisdiction where the pharmacist is working.

(i) The pharmacist-in-charge of the requesting pharmacy must ensure compliance with the applicable requirements of AS 08.80 and this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.158
AS 08.80.030

12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY. (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy services without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient’s agent, the filling pharmacy or filling pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container, the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall maintain manual or electronic records identifying, individually for each order processed, filled or dispensed,

(1) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services that distributes prescription drug orders under 12 AAC 52.235 using a pharmacy technician who holds a national certification shall maintain manual or electronic records identifying, individually for each order processed, filled, or distributed

(1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

ARTICLE 5.
PHARMACY PRACTICE STANDARDS.

Section

12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug orders by

(1) keeping the original hard copy prescription drug order presented by a patient;

(2) keeping a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal;

(3) keeping a prescription drug order put into writing either manually or electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION. (a) Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the following information:

(1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;

(2) address of the patient unless the prescription drug order is for a noncontrolled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;

(3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;

(4) name and strength of the drug prescribed;

(5) quantity prescribed;

(6) directions for use;

(7) date of issue;

(8) refills authorized, if any;

(9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;

(10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature; and

(11) if the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, a pharmacist shall add the following information to the prescription drug order:

(1) unique identification number of the prescription drug order;

(2) initials or identification code of the dispensing pharmacist;

(3) quantity dispensed, if different from the quantity prescribed;

(4) date of dispensing, if different from the date of issue;

(5) if the drug was prescribed by generic name or if an equivalent drug product other than the one prescribed was dispensed, for the drug product actually dispensed, at least one of the following:

(A) the name of the drug product’s manufacturer or distributor;

(B) the national drug code number;
(C) the short name code; or
(D) the trade name.

(c) After oral consultation with the prescribing practitioner, a pharmacist may add the following information to schedule II controlled substance prescriptions:
(1) date of issue of the prescription;
(2) address of the patient;
(3) strength of the drug prescribed;
(4) drug dosage form;
(5) drug quantity prescribed;
(6) directions for use;
(7) DEA registration number.

(d) After oral consultation with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any modification to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribed.

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.465. CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS. A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for

(1) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 C.F.R. 1306.13; or

(2) a patient who is not terminally ill or residing in a long term care facility if

(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;

(C) each partial fill is electronically documented in the patient record;

(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(E) each partial fill only occurs at the pharmacy where the original prescription order is on file.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.470. REFILLS. (a) Repealed 4/3/2020.

(b) Repealed 4/3/2020.

(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.

(d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the

(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; and

(2) drug is not a federal or state scheduled controlled substance.

(e) To indicate that an increased supply may not be dispensed under this section, a prescriber may indicate "no change to quantity", or words of similar meaning, on the prescription drug order.

(f) Nothing in this section requires a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit.

(g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,

(1) "existing" means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;

(2) "chronic" means a drug that the patient takes regularly, for greater than three months.

(h) Under (g) of this section, the pharmacist must

(1) reduce the patient's prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;

(2) document "continuation of therapy", "COT", or words of similar meaning on the prescription drug order; and

(3) file and maintain the prescription in accordance with 12 AAC 52.450.

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.480. LABELING. One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

(1) name, address, and phone number of the dispensing pharmacy;

(2) unique identification number of the prescription drug order;

(3) date the prescription drug order is dispensed;

(4) initials, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(5) name of the prescribing practitioner;

(6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;

(7) directions for use;

(8) quantity dispensed;

(9) appropriate ancillary instructions or cautions;

(10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner;

(12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent.

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION. (a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

(1) name, address, and telephone number of the prescribing practitioner;

(2) electronic signature or manual signature of the prescribing practitioner;

(3) the information required in 12 AAC 52.460(a)(1) - (8); and

(4) any other information required by federal law.

(b) A pharmacist may dispense a prescription that has been received electronically.

(c) The system for electronic transmission of prescriptions must address the following:

(1) patient's choice of pharmacy; the system may not restrict the patient's choice of pharmacy;

(2) security of the system; the system must have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information; the system must include

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other applicable equipment from an unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control, and audit access to confidential patient information; and

(D) processes to prevent unauthorized access to the prescription information when transmitted electronically;

(3) confidentiality of patient information; the system must maintain the confidentiality of patient information consistent with state and federal laws;

(4) authentication; to be valid prescriptions transmitted by an authorized prescriber or the prescribing practitioner's authorized agent from computer to a facsimile machine or from computer to computer must use an electronic signature; the prescribing practitioner's system must authenticate the sender's authority and credentials to transmit a prescription to a pharmacy and

(A) the prescribing practitioner's system must provide an audit record of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(B) the right of the board to access the prescribing practitioner's electronically transmitted prescriptions for purposes of investigations;

(5) a prescribing practitioner's system that utilizes intermediaries in the electronic communication of prescriptions to pharmacies is responsible to ensure that the contracts with the intermediaries require security measures that are equal to or better than those provided by this section and prohibit the modification of a record of a prescription after it has been transmitted by the prescribing practitioner to the pharmacist;

(6) if a paper copy prescription that is generated by the pharmacist or pharmacy technician from the electronic prescription system is printed, an electronic signature may be substituted for a manual signature;

(7) the system must maintain the integrity and confidentiality of patient information transmitted electronically for its system as required by this chapter, other state law, and federal law.

(d) In this section,

(1) "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription;

(2) "electronic transmission of prescriptions" means the communication from an authorized prescribing practitioner or the prescribing practitioner's authorized agent to a pharmacy of the patient's choice, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with this section, other state law, and federal law;

(3) "security" means a system to maintain the confidentiality and integrity of prescription information, including

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other pertinent equipment from unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control and audit access to confidential patient information; and

(D) processes for its system to prevent unauthorized access to the prescription information when transmitted electronically.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER. (a) For the purpose of dispensing a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. The transfer must be communicated directly between two licensed pharmacists.

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or by means of facsimile between pharmacies without limitation up to the number of originally authorized refills.

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) repealed 4/3/2020;

(2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:

(A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;

(B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the prescription drug order information;

(C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(D) the date of the transfer;

(4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:

(A) the original date of issue;

(B) the original unique identification number of the prescription;

(C) the quantity of drug or device remaining;

(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

(e) A pharmacy using an automated data processing system shall meet the same requirements for a manual prescription drug order transfer listed in (d) of this section.

(f) If two or more pharmacies use a common electronic database for prescription record keeping, prescription drug orders may be refilled at any of the pharmacies using the common electronic database if provisions are made

(1) for an audit trail that documents the location of each filling; and

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.510. SUBSTITUTION. (a) A pharmacist or pharmacist intern may dispense an equivalent drug product or interchangeable biological product instead of the prescribed drug if

(1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording indicating that the practitioner does not want it substituted;

(2) the patient is notified and consents to the substitution;

(3) repealed 10/31/2019; and

(4) for the drug product actually dispensed, the pharmacy record contains one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the term "equivalent drug product" or "interchangeable biological product" is defined in AS 08.80.480.

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product if there is nothing on the prescription drug order from the prescribing practitioner that indicates that the practitioner wants only the substituted product dispensed.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK). (a) Instead of dispensing one or more prescribed drug products in separate containers, a pharmacist may, with the written consent of the patient, patient's caregiver, or prescribing practitioner, provide a customized patient medication package or patient med-pak.

(b) A patient med-pak is a series of containers prepared by a pharmacist for a specific patient containing one or more prescribed solid oral dosage forms and designed or labeled to indicate the day and time, or period of time, when the contents within each container are to be taken.

(c) The pharmacist shall prepare a label for a patient med-pak that includes

(1) the name of the patient;

(2) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for the drug products in the patient med-pak;

(3) the name, strength, physical description or identification, and total quantity of each drug product in the patient med-pak;

(4) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product in the patient med-pak;

(5) any other information, statements, or warnings required or appropriate for any of the drug products in the patient med-pak;

(6) the name of the prescribing practitioner of each drug product in the patient med-pak;

(7) the date of preparation of the patient med-pak and the expiration date assigned to the patient med-pak; the expiration date may not be more than 60 days from the date of preparation of the patient med-pak;

(8) the name, address, and telephone number of the pharmacy; and

(9) the initials of the dispensing pharmacist.

(d) If the patient med-pak allows for the removal or separation of the intact containers from the patient med-pak, the pharmacist shall label each individual container of the patient med-pak to identify each of the drug products contained in the patient med-pak.

(e) When preparing a patient med-pak, the dispensing pharmacist shall take into account any applicable compendium requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container in the med-pak and any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(f) In addition to any individual prescription filing requirements, the pharmacist shall make and file a record of each patient med-pak. Each record must contain

(1) the name and address of the patient;

(2) a unique identification number for the patient med-pak itself and a separate, unique, identification number for each of the prescription drug orders for each drug product contained in the patient med-pak;

(3) information identifying or describing the design, characteristics, or specifications of the patient med-pak that is sufficient to prepare an identical patient med-pak for the patient;

(4) the date of preparation of the patient med-pak and the expiration date assigned;

(5) any special labeling instructions; and

(6) the name or initials of the pharmacist who prepared the patient med-pak.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.530. RETURN OR EXCHANGE OF DRUGS. (a) A pharmacy or pharmacist may accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed if

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or the medication was recalled by the manufacturer or the United States Food and Drug Administration; and

(2) the drug is segregated from the normal pharmacy inventory and may not be dispensed.

(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

(1) the pharmacist can readily determine that there has been no entry or attempt at entry to the unit dose package or blister card;

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the standards of the United States Pharmacopoeia (1995 revision) for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(3) the drug has not come into the physical possession of the person for whom it was prescribed, and control of the drug is known to the pharmacist to have been the responsibility of a person or persons licensed to prescribe, dispense, or administer drugs; and

(4) the drug labeling or packaging has not been altered or defaced, and the identity of the drug, its strength, lot number, and expiration date are retrievable.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: A copy of the United States Pharmacopoeia may be obtained from the United States Pharmacopoeial Convention, Inc., P.O. Box 560, Williston, VT 05495.

12 AAC 52.540. NOTIFICATION OF THEFT OR SIGNIFICANT LOSS. If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.550. ADVERTISING. A pharmacy may advertise prescription drug prices if the advertisement contains all of the following information:

(1) proprietary, trade, or generic name of the drug product;

(2) name of the manufacturer or distributor of the drug product;

(3) dosage form and strength of the drug product;

(4) price charged for a specific quantity of the drug product; and

(5) the hours that pharmaceutical services are available from the advertiser.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS. (a) A licensed pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a manner that makes the drugs unfit for human consumption.

(b) A drug that is a controlled substance shall be disposed of in accordance with federal statutes and regulations.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.570. DRUG REGIMEN REVIEW. (a) A pharmacist shall perform a drug regimen review, as defined in AS 08.80.480, for each prescription drug order.

(b) If a pharmacist identifies any of the items listed in AS 08.80.480 during the drug regimen review, the pharmacist shall avoid or resolve the problem by consulting with the prescribing practitioner, if necessary.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.580. DATA PROCESSING SYSTEMS. A pharmacy may use an automated data processing system to maintain the records required in AS 08.80 and this chapter if the system

(1) is capable of on-line retrieval of all information required in 12 AAC 52.460, 12 AAC 52.470, and 21 C.F.R. 1306.22, as amended as of February 6, 1997;

(2) is capable of producing an audit trail printout for all dispensing of any specified strength and dosage form of a drug; and

(3) has adequate safeguards to prevent loss of data and reasonable security to prevent unauthorized access to, modification of, or manipulation of patient records.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.585. MANDATORY PATIENT COUNSELING. (a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

(1) the name and description of the prescribed drug;

(2) the dosage and the dosage form;

(3) the method and route of administration;

(4) the duration of the prescribed drug therapy;

(5) any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;

(6) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;

(7) patient techniques for self-monitoring of the drug therapy;

(8) proper storage;

(9) prescription refill information; and

(10) the action to be taken in the event of a missed dose.

(b) A pharmacist shall counsel the patient or the patient's agent face-to-face. If face-to-face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist's own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopoeia Drug Information or comparable information.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient's caregiver refuses the counseling.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.590. PREPACKAGING OF DRUGS. For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

(1) the name, address, and telephone number of the pharmacy;

(2) the name, strength, and quantity of the drug;

(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;

(4) cautionary information required for patient safety and information; and

(5) the initials of the pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

ARTICLE 6.
WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

Section

12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a wholesale drug distributor

license. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The board will issue a wholesale drug distributor license to an applicant who

(1) submits a completed, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provides the name and the resume of the facility manager who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submits

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; or

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, if the applicant is a wholesale drug distributor located outside of this state.

(c) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (b) of this section; and

(2) be registered with the DEA.

(d) Within 30 days after a change in location, ownership, or facility manager, the new facility manager must

(1) submit the completed change of facility manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (b)(4) and (6) of this section.

(e) When a wholesale drug distributor ceases operations, the facility manager of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.159 AS 08.80.480

12 AAC 52.620. WHOLESALE DRUG FACILITIES. (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid license under AS 08.80.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.159 AS 08.80.480

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR OTHER DISCIPLINARY ACTION. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated facility manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159 AS 08.80.480

12 AAC 52.630. DRUG STORAGE. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements to help ensure that the identity, strength, quality, and purity of the products are not affected.

(b) A wholesale drug distributor shall ensure that a separate quarantine storage area is provided for drugs that are deteriorated, outdated, damaged, misbranded, adulterated, or are in a secondary container that has been opened or the seal of which has been broken.

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES. A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs;

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;

(7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS. (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.650. RECORDS AND INVENTORIES. (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

(1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;

(2) the identity and quantity of the drug received, distributed, or disposed of; and

(3) the date of receipt and of distribution or other disposition.

(b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS. (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.695. PROVISIONS NOT APPLICABLE. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) any of the following transfers of a drug, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee during any 12-consecutive-month period:

(A) the sale of a drug by a retail pharmacy to another retail pharmacy or to a practitioner, or the offer by a retail pharmacy to sell a drug to another retail pharmacy or to a practitioner;

(B) the purchase of a drug by a retail pharmacy or by a practitioner from another retail pharmacy, or the offer by a retail pharmacy or by a practitioner to purchase a drug from another retail pharmacy;

(C) the trade of a drug by a retail pharmacy with another retail pharmacy, or the offer by a retail pharmacy to trade a drug with another retail pharmacy;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.159
AS 08.80.030

12 AAC 52.696. OUTSOURCING FACILITIES. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements of (b) of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(g) Outsourcing facility personnel shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility must be registered as an outsourcing facility with the United States Food and Drug Administration under Sec. 503b, P.L. 113 – 54 (Drug Supply Chain Security Act).

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.697. THIRD-PARTY LOGISTICS PROVIDERS. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department

(d) The facility manager of a third-party logistics provider that has changed its name or physical address must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider must permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

ARTICLE 7.
INSTITUTIONAL PHARMACIES.

Section

12 AAC 52.700. INSTITUTIONAL PHARMACIES. Repealed 2/26/2000.

12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY. (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;

(B) name, strength, and amount of the drug;

(C) date and time of removal; and

(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical, to check the stock container or similar unit dose package of the drug removed; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS. (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the
(A) name, address, and telephone number of the institutional facility;
(B) name, strength, and quantity of the drug;
(C) cautionary information required for patient safety and information;
(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and
(E) initials of the pharmacist;
(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and
(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the
(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.

(c) Prepackaged medications shall be kept in a secure place within the emergency room.

(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.

(e) This section does not apply to the administration of a single dose to a patient.

(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL. (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

ARTICLE 8.
DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

Section

12 AAC 52.800. DRUG ROOM LICENSE. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 AS 08.80.390

12 AAC 52.810. PHARMACIST REQUIRED. An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST. A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.840. FIRST DOSE KITS. (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.850. EMERGENCY DISTRIBUTION. In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.390 AS 08.80.480

ARTICLE 9.
CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE. (a) A prescriber shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

(b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration must be completed not later than 30 days after initial licensure if the pharmacist's practice is expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a PDMP dispensation exemption form provided by the board. A pharmacist who submitted a dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.860. ACCESS TO AND CONDITIONS FOR USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM DATABASE. (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes in AS 17.30.200(d)(1) of an inquiry under a search warrant, subpoena, or order issued by an administrative law judge or a court,

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

(2) "personnel of another board or agency" means an employee of this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(c) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(1) employees of the Department of Commerce, Community, and Economic Development, assigned to the Board of Pharmacy, and providing PDMP data storage or data management services; or

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

(d) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an agent or employee to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(e) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom that department's commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(t), a pharmacist must submit information required under AS 17.30.200(b), if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily as of the previous submission date.

(c) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(d) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(f) Unless excused from reporting under AS 17.30.200(t), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(g) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a pharmacist or practitioner must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

(c) The department may not grant a waiver under this section unless the pharmacist or practitioner first agrees in writing that, if the waiver is granted, the pharmacist or practitioner will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board on at least a daily basis using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the pharmacist or practitioner files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A pharmacist or practitioner must inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS. (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a $10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880. REPORTS. (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

(1) the date on which the request was received;

(2) the name of the patient and the patient's date of birth;

(3) the name, title, and address of the individual requesting the profile;

(4) the date on which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.885. PURGED DATABASE RECORDS. The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890. GROUNDS FOR DISCIPLINE. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a practitioner not licensed by this board shall be reported to the practitioner’s licensing board.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.895. CORRECTING INFORMATION IN DATABASE. (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

(1) on a form or in a format prescribed by the board,

(A) a description of the information asserted to be incorrect, and the correction requested;

(B) the mailing and physical address and telephone number of the requester; and

(C) a signed, sworn statement attesting to the truth of the corrected information;

(2) documentation to support the correction requested; and

(3) proof of the requester's identity.

(b) If the board determines that it

(1) has sufficient information to make a determination, the board will

(A) notify the requester that the request is granted; or

(B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;

(2) lacks sufficient information to grant or deny the request, the board

(A) will request additional information from the requester; and

(B) will not act on the request until after the additional information is received.

(c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

Authority: AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

ARTICLE 10.
DISCIPLINARY GUIDELINES.

Section

12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES. The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board's disciplinary policies are known and are administered consistently and fairly.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.910. VIOLATIONS. (a) A person who is licensed under AS 08.80 and this chapter who, after a hearing under AS 44.62 (Administrative Procedure Act), is found to have violated a provision of AS 08.80 or this chapter is subject to the disciplinary penalties listed in AS 08.01.075, including public notice of the violation and penalty in appropriate publications.

(b) Nothing in the guidelines set out in 12 AAC 52.920 prohibits the board from imposing greater or lesser penalties than those described in 12 AAC 52.920 or restricting the practice of a licensee depending upon the circumstances of a particular case.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.920. DISCIPLINARY GUIDELINES. (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;
(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;
(9) operating a pharmacy in an unsanitary manner;
(10) making a false or fraudulent claim concerning a drug;
(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;
(12) violating the provisions of a board order or memorandum of agreement;
(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;
(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:
(A) a pharmacist-in-charge of a pharmacy;
(B) a sole proprietor or individual owner of a pharmacy;
(C) a partner in the ownership of a pharmacy; or
(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;
(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;
(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;
(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;
(18) violating AS 08.80.315 dealing with the confidentiality of records;
(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;
(20) offering, giving, soliciting, or receiving compensation for referral of a patient;
(21) violating AS 08.80.261(a)(3); or
(22) violating AS 17.30.200 or a regulation adopted under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.

(b) The board will, in its discretion, revoke a license if the licensee
(1) commits a violation that is a second offense;
(2) violates the terms of probation from a previous offense;
(3) violates AS 08.80.261(a)(1) or (4);
(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;
(5) is professionally incompetent if the incompetence results in risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee
(1) wilfully or repeatedly violates AS 08.80 or this chapter; or
(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

Authority: AS 08.01.075 AS 08.80.005 AS 08.80.030 AS 08.80.261 AS 08.80.315 AS 08.80.460 AS 17.30.200

12 AAC 52.925. GROUNDS FOR DENIAL OR DISCIPLINE FOR CRIMINAL HISTORY. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant's or licensee's ability to practice competently and safely include
(1) murder;
(2) manslaughter;
(3) criminally negligent homicide;
(4) assault;
(5) sexual assault;
(6) sexual abuse of a minor;
(7) unlawful exploitation of a minor, including possession or distribution of child pornography;
(8) incest;
(9) indecent exposure;
(10) robbery;
(11) extortion;
(12) stalking;

(13) kidnapping;
(14) theft;
(15) burglary;
(16) forgery;
(17) endangering the welfare of a child;
(18) endangering the welfare of a vulnerable adult;
(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;
(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52.930. TERMS OF PROBATION. The board will, in its, discretion, subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:

(1) obey all laws pertaining to the practice of pharmacy in this state;
(2) fully comply with the probation program established by the board and cooperate with representatives of the board;
(3) notify the board in writing of the dates of departure and return if the licensee leaves the state to reside or practice pharmacy outside the state;
(4) report in person at meetings of the board or to its designated representatives during the period of probation, as directed by the board;
(5) submit written reports and verification of actions as required by the board during the period of probation;
(6) if employed in the practice of pharmacy at any time during the period of probation, have the employer submit to the board verification that the employer understands the conditions of probation;
(7) be employed as a pharmacist only in a setting in which full supervision is provided and not personally act as a supervisor.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.940. USE OF ALCOHOL OR CONTROLLED SUBSTANCES. (a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for the habitual abuse of alcohol or illegal use of controlled substances may also be subject to one or more of the following:

(1) physical and mental health examinations as determined by the board to evaluate the licensee's ability to perform the professional duties of a pharmacist;
(2) as determined by the board, participation until completion in an ongoing program of rehabilitative counseling, Alcoholics Anonymous, Narcotics Anonymous, or an impaired practitioner group that includes progress reports from the care provider when requested by the board;
(3) abstaining from the personal use of alcohol or controlled substances in any form except when lawfully prescribed by a practitioner licensed to practice in Alaska;
(4) submitting to tests and samples required for the detection of alcohol or controlled substances at the request of the board or the board's representative.

(b) Access to a controlled substance in the work setting will, in the board's discretion, be restricted.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.950. PROBATION TERMS FOR PROFESSIONAL INCOMPETENCE. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation after being found professionally incompetent may be subject to one or more of the following terms of probation:

(1) successful completion of an appropriate course or courses in pharmacy, as determined by the board, before the end of the probationary period; or
(2) participation in 15 contact hours of appropriate continuing education in pharmacy.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.960. MENTAL OR PHYSICAL DISABILITIES. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for practicing or attempting to practice pharmacy while afflicted with a physical or mental illness, deterioration, or disability that interferes with the licensee's performance of pharmacy may be subject to a physical or mental health examination to evaluate the

licensee's ability to perform the professional duties of a pharmacist and if medically determined to be necessary, may be required to participate in and complete a recommended treatment program that includes written progress reports from the care provider when requested by the board.

Authority: AS 08.01.075 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.970. REINSTATEMENT OF A SUSPENDED LICENSE. The board may reinstate a suspended license only if the requirements of the suspension order have been met.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.980. REINSTATEMENT OF A REVOKED LICENSE. (a) One year after revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

(b) The applicant for reinstatement shall appear before the board.

(c) The board will, in its discretion, impose restrictions upon the pharmacist or pharmacy when reinstating a license.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

ARTICLE 11.
GENERAL PROVISIONS.

Section

12 AAC 52.985. EMERGENCY PREPAREDNESS. (a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor that results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

(b) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) Repealed 4/3/2020.

(d) Repealed 4/3/2020.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110.

(f) During a disaster emergency declared by the governor of this state,

(1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;

(2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the date that the disaster emergency ends;

(3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.990. DISPLAY OF LICENSE CERTIFICATE. A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee shall display the department's Internet web site posting confirming licensure. The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: The current posting confirming licensure can be found at the Internet web site of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing: www.commerce.state.ak.us/occ/search3.htm.

12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT. (a) A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee not later than 30 days after the date of the disciplinary decision or conviction.

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315
AS 08.80.005 AS 08.80.261 AS 08.80.460

12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;
(B) diseases that may be prevented by vaccination or immunization;
(C) current CDC immunization schedules;
(D) vaccine storage and management;
(E) informed consent;
(F) physiology and techniques for administration of immunizations;
(G) pre-immunization and post-immunization assessment and counseling;
(H) immunization reporting and records management; and
(I) identifying, responding to, documenting, and reporting adverse responses;

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;

(3) who has not administered a vaccine during the past 10 years must complete a course as described in (1) of this subsection before administering a vaccine; and

(4) must adhere to 12 AAC 52.320, including continuing education requirements under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory, and that is carried by the pharmacist if providing off-site immunizations:

(A) oral and injectable diphenhydramine; and
(B) adult and pediatric auto-inject epinephrine devices, or injectable epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed; the manual must

(A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;
(B) document that the policy and procedures manual has been reviewed and updated annually;
(C) address how vaccine related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);
(D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;
(E) address proper disposal of used or contaminated supplies;
(F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions, including the administration of related emergency medications; and
(G) detail how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern must

(1) have completed an ACPE-accredited immunization course or other comparable course that meets the requirements of (a)(1) of this section;

(2) maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training; and

(3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(d) A pharmacist or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

(f) For purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if

(1) the pharmacist meets the requirements of this chapter and is the prescriber and administrator of the vaccine; or

(2) a pharmacist intern meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern is the prescriber.

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.

(h) In this section,

(1) "CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;

(2) "FDA" means the United States Food and Drug Administration.

Authority: AS 08.01.075 AS 08.80.168 AS 08.80.480
AS 08.80.030 AS 08.80.261

12 AAC 52.993. EXECUTIVE ADMINISTRATOR. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance must be reviewed by a board member;

(2) attend state or national meetings or conferences on behalf of the board;

(3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;

(4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;

(5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

12 AAC 52.994. INDEPENDENT DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS. (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall

(1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;

(2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and

(3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.

(b) A pharmacist may

(1) supply an opioid overdose drug as

(A) an intramuscular injection;

(B) an intranasal spray;

(C) an auto-injector; or

(D) any other product forms approved by the United States Food and Drug Administration; and

(2) recommend other optional items when appropriate, including

(A) alcohol pads;

(B) rescue breathing masks; or

(C) rubber gloves.

(c) When dispensing an opioid overdose drug

(1) the pharmacist shall

(A) label the drug in accordance with 12 AAC 52.480;

(B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";

(C) ensure that the label includes directions to call 911 or other available emergency services; and

(D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450;

(2) the pharmacist may

(A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including

(i) dosing;

(ii) administration;

(iii) effectiveness;

(iv) adverse effects;

(v) storage conditions;

(vi) shelf life; and

(vii) safety;

(B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.

(d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or 12 AAC 52.490.

(e) In this section,

(1) "opioid overdose drug"

(A) has the meaning given in AS 08.80.168;

(B) includes naloxone hydrochloride;

(2) "recipient" means the person to whom an opioid overdose drug is furnished.

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480

12 AAC 52.995. DEFINITIONS. (a) In this chapter, unless the context requires otherwise,

(1) "ACPE" means Accreditation Council for Pharmacy Education;

(2) "approved program" means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved or accredited provider;

(3) "approved provider" means an individual, institution, organization, association, corporation, or agency offering an approved program under 12 AAC 52.340 and is not an accredited provider;

(4) "authorized inspector" means a member of the board or an investigator with the division assigned occupational licensing functions in the department;

(5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(6) "blood component" means that part of blood separated by physical or mechanical means;

(7) "board" means the Alaska Board of Pharmacy;

(8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;

(9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;

(10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;

(11) "DEA" means the United States Drug Enforcement Administration;

(12) "department" means the Department of Commerce, Community, and Economic Development;

(13) "direct supervision" means supervision that insures adequate safety controls either by personal supervision or through a telepharmacy system;

(14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;

(15) "institutional facility" means a

(A) hospital;

(B) long-term care facility, including a nursing home, convalescent home, or other related facility;

(C) mental health facility;

(D) rehabilitation center;

(E) psychiatric center;

(F) developmental disability center;

(G) drug abuse treatment center;

(H) family planning clinic;

(I) penal institution;

(J) hospice; or

(K) public health facility;

(16) "institutional pharmacy" means a pharmacy located in an institutional facility;

(17) "licensee" means a person who is licensed under AS 08.80 and this chapter;

(18) “live program” means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;

(19) “sterile pharmaceutical” means a drug dosage form free from living microorganisms (aseptic);

(20) “wholesale distribution” means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in 12 AAC 52.695;

(21) “central pharmacy” means a pharmacy providing remote pharmacy services through a telepharmacy system;

(22) “personal supervision” means supervision that includes visual or physical proximity to ensure adequate safety controls;

(23) “pharmacy” includes a central pharmacy and a remote pharmacy;

(24) “remote pharmacy” means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

(25) “still image capture” means a specific image captured electronically from a video or other image capture device;

(26) “store and forward” means a video or still image record that is saved electronically for future review;

(27) “telepharmacy system” means a system under the direct supervision of a licensed pharmacist that monitors the dispensing and distribution of prescription drugs and provides for related drug use review and patient counseling services through a computer link and a video link with sound;

(28) “accredited provider” means an individual, institution, organization, association, corporation, or agency that is recognized by the ACPE as able to provide quality continuing education programs;

(29) “filling pharmacist” means a pharmacist participating in shared pharmacy services that processes or fills a prescription order for a patient;

(30) “filling pharmacy” means a pharmacy participating in shared pharmacy services that processes or fills a prescription order for a patient;

(31) “requesting pharmacist” means a pharmacist participating in shared pharmacy services that forwards a prescription order to another participating pharmacy or pharmacist to be processed or filled;

(32) “requesting pharmacy” means a pharmacy participating in shared pharmacy services that forwards a prescription order to another participating pharmacy to be processed or filled;

(33) “shared pharmacy services” means a system allowing the processing by a participating pharmacist or a pharmacy of a request from another participating pharmacist or pharmacy to enter or review a prescription drug order or process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

(34) “dispenser” means a practitioner who delivers a controlled substance to an ultimate user or research subject under the lawful order of a practitioner; in this paragraph, "delivers" includes the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery;

(35) “profile” means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance;

(36) “PDMP” means the prescription drug monitoring program’s controlled substance prescription database;

(37) “moral turpitude” includes conduct that is considered contrary to community standards of justice, honesty, or good morals;

(38) “pharmacy technician who holds a national certification” means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA).

(b) In AS 08.80.315(3), “other persons or governmental agencies” include investigators for the department who are assigned to conduct investigations under AS 08.

(c) In AS 08.80.030(b)(7), “monitoring of drug therapy” means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. “Monitoring of drug therapy” includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

(d) In AS 17.30.200 and 12 AAC 52.855 – 12 AAC 52.895, “practitioner” has the meaning given in AS 11.71.900.

(e) In 12 AAC 52.610 – 12 AAC 52.697, “facility manager” means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.159 AS 11.71.900 AS 17.30.200 AS 17.30.900

CHAPTER 30.
CONTROLLED SUBSTANCES

Sec. 17.30.200. Controlled substance prescription database. (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (t) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (t) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; or

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(*l*) A person

(1) with authority to access the database under (d) of this section who knowingly

(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;

(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;

(C) allows another person who is not authorized to access the database to access the database commits a class C felony;

(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.

(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures

(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to

(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;

(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;

(C) increase coordination among prescription drug monitoring program partners;

(D) involve stakeholders in the planning process;

(2) shall include information related to the

(A) security of the database; and

(B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.

(n) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (n) of this section.

(p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section

(1) must be provided to the practitioner;

(2) is confidential;

(3) may not disclose information that is confidential under this section;

(4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.

(q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.

(r) The Department of Commerce, Community, and Economic Development shall

(1) assist the board and provide necessary staff and equipment to implement this section; and

(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (n) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

(A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and

(B) consult with the board to establish the fees under this paragraph.

(s) Notwithstanding (p) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is

(1) administered to a patient at

(A) a health care facility; or

(B) a correctional facility;

(2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(A) inpatient pharmacy; or

(B) emergency department.

(u) In this section,

(1) "board" means the Board of Pharmacy;

(2) "database" means the controlled substance prescription database established in this section;

(3) "knowingly" has the meaning given in AS 11.81.900;

(4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;

(5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.

General Requirements.

(a) Each pharmacy is of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparation of prescription drug orders.

(b) There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(c) The prescription department and all areas where drugs are stored are well lighted, well ventilated, dry, and maintained in a clean and orderly condition. Walls, floors, ceilings, and windows are clean and in general good repair and order.

(d) Each pharmacy has a sink with hot and cold running water within the pharmacy and maintained in a sanitary condition.

(e) There are refrigeration facilities with a thermometer in the prescription department for the proper storage of drugs requiring refrigeration. Temperatures in the refrigerator are maintained within United States Pharmacopeia standards.

(f) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.

Equipment and Supplies.

(a) All pharmacies have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(b) All equipment is kept in a clean and orderly manner. Equipment used in the compounding or preparation of prescription drug orders (counting, weighing, measuring, mixing, stirring, and molding equipment) is clean and in good repair.

Library. A reference library is maintained which includes the following:

(1) A current copy (hard-copy or electronic media access) of the Alaska Pharmacy Statutes and Regulations.

(2) At least one current or updated reference (hard-copy or electronic media access) from each of the following categories:

(A) Patient information – examples are;

(i) USP Dispensing Information; or

(ii) Patient Drug Facts; or

(iii) reference text or information leaflets which provide patient information.

(B) General information – examples are;

(i) Facts and Comparisons; or

(ii) USP Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or

(iii) Remington's Pharmaceutical Sciences.

(C) Clinical Information – examples are;

(i) AHFS Drug Information; or

(ii) Micromedex; or

(iii) Clinical Pharmacology; or

(iv) reference material pertinent to the practice setting.

(3) The telephone number of the nearest poison control center is readily available.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines on facilities, reference materials, equipment, supplies and other matters. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.400.

STERILE PHARMACEUTICALS
February 2008

Scope and Purpose.

The purpose of this pamphlet is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (eg. home, hospital, extended care facility, hospice, practitioner's office).

Definitions.

(a) "Biological Safety Cabinet" – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(b) "Class 100 Environment" – an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209D.

(c) "Cytotoxic" – a pharmaceutical that has the capability of killing living cells.

(d) "Parenteral" – a sterile preparation of drugs for injection through one or more layers of the skin.

(e) "Sterile Pharmaceutical" – dosage form free from living micro-organisms (aseptic).

Policy and Procedure Manual.

(a) A policy and procedure manual is prepared and maintained for the compounding, dispensing, and delivery of sterile pharmaceutical drug orders. The manual is reviewed and revised as necessary on an annual basis by the pharmacist-in-charge and is available for inspection at the pharmacy.

(b) The manual includes policies and procedures, as applicable, for:

(1) Clinical services;
(2) Sterile product handling, preparation, dating, storage and disposal;
(3) Major and minor spills of cytotoxic agents;
(4) Disposal of unused supplies and medications;
(5) Drug destruction and returns;
(6) Drug dispensing;
(7) Drug labeling;
(8) Duties and qualifications for professional and nonprofessional staff;
(9) Equipment use and maintenance;
(10) Handling of infectious waste pertaining to drug administration;
(11) Infusion devices and drug delivery systems;
(12) Training and orientation of professional and non-professional staff commensurate with the services provided;
(13) Dispensing of investigational medications;
(14) Quality control and quality assurance;
(15) Recall procedures;
(16) Infection control;
(17) Suspected contamination of sterile products;
(18) Orientation of employees to sterile technique;
(19) Sanitation;
(20) Security; and
(21) Transportation.

Physical Requirements.

(a) The pharmacy designates an area for the preparation of sterile products that is functionally separate from areas for the preparation of non-sterile products and is constructed to minimize traffic and airflow disturbances. It is used only for the preparation of these specialty products. It is of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy preparing parenteral products has:

(1) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environments during normal activity;

(2) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biological safety cabinets;

(3) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand washing prior to compounding;

(4) The designated area shall have hard cleanable surfaces, walls, floors and ceilings;

(5) Appropriate disposal containers for used needles, syringes, etc. and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patient's homes;

(6) Refrigerator/freezer with thermometer;

(7) Temperature controlled delivery container, if appropriate;

(8) Infusion devises, if appropriate;

(9) Supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(c) Laminar flow hood certification (or clean room certification, if applicable) are conducted at least every six months by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports are maintained for at least two years. In addition, prefilters are replaced on a regular basis and the replacement date documented.

(d) The pharmacy has current reference materials related to sterile products. These reference materials will contain information on stability, incompatibilities, preparation guidelines, and the handling of chemotherapy drug products.

Personnel.

(a) All personnel participating in the preparation and/or dispensing of compounded sterile pharmaceuticals are trained in this specialized function, including the principles of aseptic technique. All duties and responsibilities of personnel are consistent with their training and experience.

(b) Pharmacies providing parenteral products to non-hospitalized patients have a pharmacist accessible twenty-four hours per day to respond to patient's and other health professional's questions and needs.

Drug Distribution and Control.

(a) In addition to labeling required for all dispensed prescription drug orders, the labeled container of a sterile pharmaceutical bears the expiration date of the preparation based upon published data.

(b) Delivery Service. The pharmacist-in-charge assures the environmental control of all products shipped. Therefore, any compounded sterile pharmaceutical is shipped or delivered to a patient in appropriate temperature controlled (as defined by United States Pharmacopeia Standards) delivery containers and stored appropriately in the patient's home or outpatient location.

(c) Disposal of Infectious/Hazardous Waste. The pharmacist-in-charge is responsible for assuring there is a system for the disposal of cytotoxic waste and infectious waste in a manner so as not to endanger the public health.

(d) Emergency Kit. When sterile pharmaceuticals are provided to home care patients, the pharmacy may supply the licensed nurse with emergency drugs, if the prescribing practitioner has authorized the use of these drugs by a protocol for use in an emergency situation (e.g. anaphylactic shock).

Cytotoxic Drugs.

The following additional requirements are necessary for those pharmacies that prepare cytotoxic drugs to assure the protection of the personnel involved:

(a) All cytotoxic drugs are compounded within a vertical flow, Class II, Biological Safety Cabinet. Policy and procedures are developed for the cleaning of the laminar airflow hood between compounding cytotoxic drugs and other parenteral products, if applicable.

(b) Protective apparel is worn by personnel compounding cytotoxic drugs. This includes disposable gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs are used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents are developed and included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Patient Training.

If appropriate, the Pharmacist demonstrates or documents the patient's training and competency in managing the type of therapy provided by the Pharmacist to the patient in the home environment. A pharmacist is involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The Pharmacist is responsible for seeing the patient's competency in the above areas is reassessed on an ongoing basis.

Quality Control and Quality Assurance Procedures.

(a) Quality Control. There is a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures are in place to assure the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures include, but are not limited to, the following:

(1) recall procedures;

(2) storage and dating;

(3) documentation of appropriate functioning of refrigerator, freezer, and other equipment;

(4) documentation of aseptic environmental control device certification and the regular replacement of prefilters;

(5) a process to evaluate and confirm the quality of the prepared pharmaceutical product; and

(6) if bulk compounding of parenteral solutions is performed utilizing non-sterile chemicals, extensive end product testing is documented prior to the release of the product from quarantine. This process includes appropriate tests for particulate matter and pyrogens.

(b) Quality Assurance.

(1) There is a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure efficient drug delivery, patient safety, and positive patient outcomes.

(2) There is documentation of quality assurance audits at regular, planned intervals which may include infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions, and drug therapy appropriateness.

(3) A plan for corrective action of problems identified by quality assurance audits is developed which includes procedures for the documentation of identified problems and action taken.

(4) A periodic evaluation of the effectiveness of the quality assurance activities is completed and documented.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.430.

(a) A pharmacist may compound drugs in limited quantities before receiving a valid prescription drug order if the pharmacist has a historical basis of valid prescription drug orders generated solely within an established relationship between the pharmacist, a patient, and a prescribing practitioner for the amount of drugs compounded. Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

(b) Compounding includes the preparation

(1) according to a prescription drug order of drugs or devices that are not commercially available;

(2) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

(c) When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription drug order or in the computerized patient medication record. The prescribing practitioner's authorization is in addition to signing to permit substitution on a prescription drug order or advising verbally that substitution is permitted. The reconstitution of commercially available products according to the manufacturer's guidelines is permissible without notice to the prescribing practitioner.

(d) A pharmacist may not offer compounded drug products to prescribing practitioners, pharmacists, or pharmacies for resale except in the course of professional practice for a prescribing practitioner to administer to an individual patient. The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is considered manufacturing.

(e) A pharmacist may receive, store, and use drug substances for compounding prescriptions that meet official compendia requirements. A pharmacist shall use the pharmacist's professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia.

PERSONNEL

A pharmacist engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.

COMPOUNDING FACILITIES

(a) A pharmacy engaging in compounding shall have a specifically designated and adequate area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area of the pharmacy must be provided. The facilities must include hot and cold water, soap or detergent, and air-driers or single use towels.

(d) The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse must be disposed of in a safe and sanitary manner.

(e) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous

cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be used in order to prevent cross-contamination.

RECORDS AND REPORTS

(a) A pharmacist shall keep records of all compounded products for two years. The records must be readily available for authorized inspection at the pharmacy.

(b) A pharmacist shall ensure that there are formulas maintained electronically or manually. A formula must include ingredients, amounts, methodology and equipment, if needed, and special information regarding sterile compounding.

(c) A pharmacy engaging in compounding must have written procedures for the compounding of drugs to assure that the finished products have the identity, strength, quality, and purity they are represented to possess. The procedures must include a listing of the components, their amounts in weight or volume, the order of component mixing, and a description of the compounding process. The procedures must list all equipment and utensils and the container or closure system relevant to the sterility and stability of the intended use of the drug. The procedures must be followed in the execution of the drug compounding procedure.

(d) A pharmacist shall accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist shall check these operations at each stage of the compounding process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another container, the new container must be identified with the component name and the weight or measure.

(e) To assure the reasonable uniformity and integrity of compounded drug products, written procedures must be established and followed that describe the tests or examinations to be conducted on the product compounded. The control procedures must be established to monitor the output and to validate the performance of those compounding processes that include the following when appropriate:

(1) capsule weight variation;

(2) adequacy of mixing to assure uniformity and homogeneity;

(3) clarity, completeness, or pH of solutions;

(f) A pharmacy engaging in compounding shall establish and follow appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile. The procedures must include validation of any sterilization process.

(g) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include

(1) the date of preparation;

(2) the lot numbers – the lot numbers may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If a lot number is assigned by the pharmacy, the pharmacy shall record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components;

(3) the expiration date of the finished product. This date may not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber or to be stored in until dispensing. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist;

(4) the signature or initials of the pharmacist performing the compounding;

(5) initials of the person preparing each process;

(6) initials of the pharmacist supervising each process;

(7) a formula for the compounded product maintained in a readily retrievable form;

(8) the name of the manufacturer of the raw materials;

(9) the quantity in units of finished products or grams of raw materials; and

(10) the package size and the number of units prepared.

(h) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in the product.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist on compounding practices. Professional conduct by a licensee includes adherence to these guidelines.
See 12 AAC 52.440.

MOTION SHEETS

EXECUTIVE SESSION MOTION

Sec. 44.62.310. Government meetings public.
(c) The following subject may be considered in an executive session:

(1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
(2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
(3) matters which by law, municipal charter, or ordinance are required to be confidential;
(4) matters involving consideration of government records that by law are not subject to public disclosure.

MOTION WORDING:

"In accordance with the provisions of Alaska Statute 44.62.310 (c), I move to go into executive session for the purpose of discussing (select the appropriate statutory citation for the situation):

(1) **matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;** ***OR***

(2) **subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;** ***OR***

(3) **matters which by law, municipal charter, or ordinance are required to be confidential;** ***OR***

(4) **matters involving consideration of government records that by law are not subject to public disclosure.**

Board staff is requested to remain during the session ***OR***
Board only to remain during session."

Staff will then state **"The board is off the record at _____(time)."**

Board or Commission: Alaska Board of Pharmacy

Meeting Date: _____

Agenda Item # _____ Tab #_____ Topic: _____

Primary Motion

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

Subsidiary Motion or Amendment

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

BOARD LIAISON TRAINING
MODULE TWO: MEETING MANAGEMENT 201

Updated August 2021

Basic *Robert's Rules of Order* for CBPL board meetings

ORDER OF OPERATIONS TO TAKE OFFICIAL ACTION AS A BOARD

1. A member seeks recognition from the chair.
2. The member is recognized by the chair and "has the floor."
3. The member makes a motion.
4. The motion is seconded (if appropriate, see chart).
5. The chair (or staff, if delegated) restates the motion to the body.
6. Board or commission debates the motion.
7. Subsidiary motions are made, if any: Amend, table, send to committee (see chart).
8. Board or commission votes on subsidiary motion, if any.
9. Board or commission votes on the main motion either by roll call or unanimous consent.
10. The chair (or staff) announces the result of the vote.

CHART OF COMMON MOTIONS

PURPOSE	YOU SAY	INTERRUPT?	2ND?	DEBATE?	AMEND?	VOTE?
Bring business before the board	I move to…	No	Yes	Yes	Yes	Majority
Modify wording of motion	I move to amend the motion by…	No	Yes	Yes	Yes	Majority
Lay aside temporarily	I move to lay the question on the table.	No	Yes	No	No	Majority
Close debate	I move the previous question.	No	Yes	No	No	2/3
Limit or extend debate	I move that debate be limited to…	No	Yes	No	Yes	2/3
Postpone to a certain time	I move to postpone the motion to…	No	Yes	Yes	Yes	Majority
Refer to committee	I move to refer the motion to…	No	Yes	Yes	Yes	Majority
Kill main motion	I move that the motion be postponed indefinitely.	No	Yes	Yes	Yes	Majority

Make follow agenda	I call for the orders of the day.	Yes	No	No	No	None or 2/3 to overrule
Take matter from table	I move to take from the table…	No	Yes	No	No	Majority
Cancel previous action	I move to rescind…	No	Yes	Yes	Yes	2/3 w/o prior notice
Reconsider motion	I move to reconsider…	No	Yes	Varies	No	Majority
Take a break	I move to recess for…	No	Yes	No	Yes	Majority
Close meeting	I move to adjourn.	No	Yes	No	No	Majority

BEST PRACTICES

Makers of motions should write them down before verbalizing, then hand the written motion to the secretary once the motion has been made on the floor.

It is appropriate for the chair to call for a brief break ("at ease") to untangle the motions when operations become confused. Do not proceed in confusion.

It is a misconception that the chair can only vote in the case of a tie. From www.robertsrules.com:

> If the chair is a member of the voting body, he or she has exactly the same rights and privileges as all other members have, including the right to make motions, to speak in debate, and to vote on all questions. So, in meetings of a small board (where there are not more than about a dozen board members present), and in meetings of a committee, the presiding officer may exercise these rights and privileges as fully as any other member.
>
> When will the chair's vote affect the result? On a vote that is not by ballot, if a majority vote is required and there is a tie, he or she may vote in the affirmative to cause the motion to prevail. If there is one more in the affirmative than in the negative, the chair can create a tie by voting in the negative to cause the motion to fail. Similarly, if a two-thirds vote is required, he or she may vote either to cause, or to block, attainment of the necessary two thirds.

Unanimous consent occurs when all members vote in favor of a motion. Sometimes unanimous consent simply occurs after a vote, when all members vote the same way. Other times, unanimous consent may be requested as part of a motion. Typically, this request happens when the person making the motion knows the item is not controversial. The person making the motion might say, "Mr. [or Madam] Chair, I move to approve the minutes from the July 2021 meeting and ask unanimous consent." The chair then asks if there is any objection. If there is none, the item is adopted by unanimous consent. Discussion may also be permitted but usually only for clarification. If there is objection, then debate occurs and the matter goes to a roll call vote.

Alaskans have to right to know how board and commission members voted, so unanimous consent should not be used to avoid debate or pressure a board into a vote. Member who are unsure how to vote should engage in debate so they may offer an informed vote. In boards where quieter members or public members shy away from engagement, the chair should always request a roll call vote to ensure their voices are not disenfranchised.

Executive session: Why? When? How?

As reviewed in Module One, all board meetings must be publicly noticed per AS 44.62.310:

> **Sec. 44.62.310. Government meetings public.**
> (a) All meetings of a governmental body of a public entity of the state are open to the public except as otherwise provided by this section or another provision of law. Attendance and participation at meetings by members of the public or by members of a governmental body may be by teleconferencing. Agency materials that are to be considered at the meeting shall be made available at teleconference locations if practicable. Except when voice votes are authorized, the vote shall be conducted in such a manner that the public may know the vote of each person entitled to vote. The vote at a meeting held by teleconference shall be taken by roll call. This section does not apply to any votes required to be taken to organize a governmental body described in this subsection.
>
> (b) If permitted subjects are to be discussed at a meeting in executive session, the meeting must first be convened as a public meeting and the question of holding an executive session to discuss matters that are listed in (c) of this section shall be determined by a majority vote of the governmental body. The motion to convene in executive session must clearly and with specificity describe the subject of the proposed executive session without defeating the purpose of addressing the subject in private. Subjects may not be considered at the executive session except those mentioned in the motion calling for the executive session unless auxiliary to the main question. Action may not be taken at an executive session, except to give direction to an attorney or labor negotiator regarding the handling of a specific legal matter or pending labor negotiations.
>
> (c) The following subject may be considered in an executive session:
> (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
> (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
> (3) matters which by law, municipal charter, or ordinance are required to be confidential;
> (4) matters involving consideration of government records that by law are not subject to public disclosure.

EXECUTIVE SESSION PROTOCOL

In reading the law above, we see that we need to do a few things to appropriately manage executive session:

1. Hold a publicly noticed meeting of the board.
2. By motion, state the statutory reason for entering executive session. (A cheat sheet is provided in PL-1.)
3. Go off record and “close the doors.”
4. Ensure the topic stays on topic during executive session.
5. By motion, exit executive session and go back on record.
6. Take any resulting action in the open meeting.

It is a best practice to have a supervisor attend this process the first few times a staff member shepherds a board through executive session. The board can state in the motion that they would like division staff to attend and should identify who they mean if it is unclear.

EXCEPTION TO PUBLIC NOTICE OF A MEETING
In accordance with 44.62.310(d), public notice of meetings called for the sole purpose of making a decision on an adjudicatory proceeding is not required. (Meeting minutes, however, are still required to record the official action taken.)

Adjudicatory proceedings include board consideration of hearing officer decisions, petitions for reconsideration filed in accordance with AS 44.62, stipulations, memoranda of agreement, license surrenders, and summary suspensions. Adjudicatory proceedings should be supervised by a seasoned investigator, executive administrator, and/or AAG. An administrative law judge will also provide procedural guidance.

Expectations of board member participation

At the very least, board members are expected to attend scheduled meetings and vote on appropriate matters via OnBoard during the interim. When board members do not meet these minimal standards of participation, important business, such as license action or regulatory progress can be delayed. Inaction by a board can impact individuals' economic welfare, a community's health care outcomes, or public safety.

If a board member fails to attend a meeting or vote online, find out why. Sometimes, absences cannot be avoided. However, nonparticipation should be rare. If the board requires review and approval of license applications, those members may need to let staff know when they may be on vacation or unavailable for extended periods. This will allow staff to set expectations for workflow and alert applicants to potential delays. Knowing whether a quorum is possible can also help investigators and administrative law judges manage urgent disciplinary matters.

Per AS 08.01,020, boards may adopt regulations providing for removal after several unexcused absences. However, a candid conversation is the best and fastest route to resolving a member's nonparticipation.

1. **First, staff should find out why the member has been missing meetings or votes.** Is it because staff's email goes to the member's spam filter? Is the member having technical difficulties such as internet connectivity or using Zoom or OnBoard? These simple matters can usually be resolved quickly and easily.

2. **When the matter goes deeper or the member is simply not responding, consult the board chair.** The chair should make a call to discuss these issues and plot a path forward. Does the workload exceed the member's expectations? Is the member having regret in saying "yes" to the commitment? Perhaps the member has a long-term family emergency that is diverting time and energy.

3. **If the board chair is unsuccessful in reaching the member or resolving the issue, discuss with your supervisor.** Sometimes the division director is the best person to reach out to the member. This discussion can often yield fruit when there is an interpersonal conflict on the board or when the member doesn't want to share their concerns with a peer.

4. **Lastly, when all else fails, the division director can reach out to the director of the Office of Boards and Commissions (B&C) for guidance.** As the appointing authority representing the governor, the B&C director can "go deep" and even withdraw appointment, if necessary.

Additional detailed information can be found in the CBPL Guide to Excellence in Regulation and PL-1 Board Meeting Handbook.

ORDER OF OPERATIONS TO ACT AS A BOARD

1. A member seeks recognition from the chair.
2. The member is recognized by the chair and "has the floor."
3. The member makes a motion.
4. The motion is seconded (if appropriate, see chart on other side).
5. The chair (or staff, if delegated) restates the motion to the body.
6. Board or commission debates the motion.
7. Subsidiary motions are made, if any: Amend, table, send to committee (see chart on other side).
8. Board or commission votes on subsidiary motion, if any.
9. Board or commission votes on the main motion either by roll call or unanimous consent.
10. The chair (or staff) announces the result of the vote.

Best practices:

1. Makers of motions should write them down before verbalizing, then hand the written motion to the secretary once the motion has been made on the floor.
2. It is appropriate for the chair to call for a brief break ("at ease") to untangle the motions when operations become confused. Do not proceed in confusion.

PURPOSE	YOU SAY	INTER-RUPT?	2ND?	DEBATE?	AMEND?	VOTE?
Bring business before the board	I move to…	No	Yes	Yes	Yes	Majority
Modify wording of motion	I move to amend the motion by…	No	Yes	Yes	Yes	Majority
Lay aside temporarily	I move to lay the question on the table.	No	Yes	No	No	Majority
Close debate	I move the previous question.	No	Yes	No	No	2/3
Limit or extend debate	I move that debate be limited to…	No	Yes	No	Yes	2/3
Postpone to a certain time	I move to postpone the motion to…	No	Yes	Yes	Yes	Majority
Refer to committee	I move to refer the motion to…	No	Yes	Yes	Yes	Majority
Kill main motion	I move that the motion be postponed indefinitely.	No	Yes	Yes	Yes	Majority
Make follow agenda	I call for the orders of the day.	Yes	No	No	No	None or 2/3 to overrule
Take matter from table	I move to take from the table…	No	Yes	No	No	Majority
Cancel previous action	I move to rescind…	No	Yes	Yes	Yes	2/3 w/o prior notice
Reconsider motion	I move to reconsider…	No	Yes	Varies	No	Majority
Take a break	I move to recess for…	No	Yes	No	Yes	Majority
Close meeting	I move to adjourn.	No	Yes	No	No	Majority